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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

MSP RECOVERY CLAIMS, SERIES LLC, a)
Delaware series limited liability company, on)
behalf of themselves and all others similarly) **CLASS ACTION COMPLAINT**
situated,)

Plaintiffs,)

Case No. 5:23-cv-1591

v.)

DEMAND FOR JURY TRIAL

JAZZ PHARMACEUTICALS, PLC; JAZZ)
PHARMACEUTICALS, INC.; JAZZ)
PHARMACEUTICALS IRELAND, LTD.;)
EXPRESS SCRIPTS, INC.; EXPRESS SCRIPTS)
HOLDING COMPANY; EXPRESS SCRIPTS)
SPECIALTY DISTRIBUTION SERVICES, INC.;)
CURAScript, INC., d/b/a CURAScript, SD;)
PRIORITY HEALTHCARE DISTRIBUTION,)
INC. d/b/a CURAScript SD AND)
CURAScript SPECIALTY DISTRIBUTION)
SD; CARING VOICE COALITION, and ADIRA)
FOUNDATION,)

Defendant(s).

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1 Plaintiffs, MSP Recovery Claims, Series LLC (“MSPRC”), on behalf of themselves and other
 2 Medicare Advantage health plans¹ and Medicaid health plans² (collectively, “Class Members”),³ sue
 3 1) Jazz Pharmaceuticals, PLC.; Jazz Pharmaceuticals, Inc.; and Jazz Pharmaceuticals Ireland, Ltd.
 4 (hereinafter collectively referred to as “Jazz”); 2) Express Scripts, Inc.; Express Scripts Holding
 5 Company; Express Scripts Specialty Distribution Services, Inc.; CuraScript, Inc., d/b/a CuraScript,
 6 SD; Priority Health Care Distribution, Inc., d/b/a CuraScript SD and CuraScript Specialty
 7 Distribution SD (hereinafter collectively referred to as “Express Scripts”), 3) Caring Voice Coalition,
 8 Inc. (“CVC”); and 4) Adira Foundation f/k/a Facilitating Patient Health (“Adira”) (hereinafter all
 9 defendants collectively referred to as “Defendants”), allege:

10 **NATURE OF ACTION**

11 1. This case arises out of Defendants’ conspiratorial schemes to increase the unit price
 12 and quantity dispensed of Xyrem, which treats both cataplexy and excessive daytime sleepiness in
 13 narcolepsy; and Prialt, which is a non-opioid, non-NSAID analgesic agent approved for the
 14 management of severe chronic pain. (Collectively, “Subject Jazz Drugs” or “Jazz Drugs”).
 15 Defendants’ schemes violated state and federal bribery laws thereby disqualifying claims for the
 16 Subject Drugs from payment. As a result, Plaintiffs’ Assignors (“Assignors”) and the Class Members
 17 paid supra-competitive prices for the Subject Jazz Drugs for tainted and unpayable claims and for
 18 artificially inflated quantities of dispensed Subject Jazz Drugs, directly to Defendant Express Scripts,
 19 on behalf of beneficiaries enrolled in their health plans (“Enrollees”).

20 2. Jazz and CVC created a Scheme to circumvent the Congressionally mandated co-
 21 payment requirements (referred to herein as “Co-Payment Scheme” or “Scheme” or “Co-Payment
 22

23 ¹ “Medicare Advantage health plans” is defined as Medicare Advantage entities such as Medicare
 24 Advantage organizations (“MAOs”), Independent Practice Associations (“IPAs”), Management
 25 Service organizations (“MSOs”), Health Maintenance organizations (“HMOs”), Part D Sponsors, and
 26 other Medicare first tier, downstream, and related entities. Throughout the Complaint, “MA Plan” is
 27 used as a shorthand for all such Medicare Advantage health plan entities.

28 ² “Medicaid health plans” is defined to include Medicaid Managed Care Organizations (“MCO”) and
 other Medicaid first tier, downstream, and related entities. Throughout the Complaint, “Medicaid
 Plans” is used as a shorthand for all such Medicaid health plan entities.

³ The full class is defined *infra*, Section VI.

1 Circumvention Enterprise”) designed to reduce sensitivity to the ever-increasing drug prices and
2 increased dispensing of Jazz Drugs.⁴

3 3. Defendants executed their Scheme, engaging in multiple overt acts effectively
4 eliminating price sensitivity constraints. This resulted in three related, cognizable economic injuries
5 as Assignors and Class Members paid significantly higher costs than they would otherwise have to
6 pay but for the schemes of the Co-Payment Circumvention Enterprise above. First, the Scheme caused
7 the Subject Jazz Drugs to be over-prescribed and over-dispensed. Second, the Scheme allowed Jazz
8 to raise their prices to supra-competitive levels. Third, the Scheme rendered claims for the Subject
9 Jazz Drugs unpayable under state and federal law and concealed this fact.

10 4. Jazz and CVC colluded and agreed that CVC would act as an illegal conduit, disguised
11 as an independent charity, by which Jazz could funnel kickbacks to pharmacies through CVC’s
12 disease funds—including a Narcolepsy Fund, with respect to Xyrem, and a Severe Chronic Pain Fund,
13 with respect to Prialt. Jazz and CVC agreed that CVC would create both funds which catered almost
14 exclusively—and at times exclusively—to the Subject Jazz Drugs.

15 5. Once a relationship between Jazz and CVC had been created, Jazz poured millions
16 into CVC, and began referring patients to CVC.

17 6. Co-conspiring pharmacies, including Express Scripts, CuraScript, Accredo
18 Therapeutics, and BioScrip (the “Specialty Pharmacies”), would also refer patients to CVC (through
19 the mail and wires), where they would then be paid by Jazz for doing so. Upon receiving copay
20 assistance from CVC (using Jazz’s funds), the Specialty Pharmacies would then generate and submit
21 claims (through the mail and wires) for payment directly to Assignors and Class Members. Despite
22 participating in the Scheme, the Specialty Pharmacies routinely used the mail and wires to submit
23 claims accompanied with false certifications of compliance with state and federal laws. This resulted
24

25 ⁴ When Medicare beneficiaries, including those covered by Medicare Advantage health plans, obtain
26 a prescription drug, the beneficiaries may be required to make a co-payment. Congress included co-
27 payment requirements in the Medicare structure, in part, to encourage market forces to serve as a
28 check on health care costs, specifically including the prices that pharmaceutical companies can
demand for their drugs. Frerick, Austin, *The Cloak of Social Responsibility: Pharmaceutical
Corporate Charity*, TAX NOTES, Vol. 153, No. 9, Nov. 28, 2016.

1 in millions of dollars paid by Assignors and Class Members for claims they otherwise would not, and
2 should not, have paid for.

3 7. As part of this Scheme, Jazz routinely obtained data from CVC detailing how many
4 patients taking each Subject Drug that CVC had assisted, how much CVC had spent on those patients,
5 and how much CVC expected to spend on those patients in the future. This information was used to
6 ensure that CVC used the purported “donations” (or “Corporate Contributions”) for Jazz Drugs only
7 and allowed Jazz to perform return on investment calculations.

8 8. Despite certifying otherwise to the OIG, Jazz and CVC routinely used the mail and
9 wire to exchange information to ensure Jazz possessed sufficient data to maximize profits from its
10 Corporate Contributions to CVC. This exchange occurred on a monthly basis in contravention of OIG
11 guidance.

12 9. Defendants also funneled Medicare Advantage Plan (“MA Plan”) and Medicaid Plan
13 patients away from Jazz’s free drug program. Defendants excluded individuals from participating in
14 Jazz’s free drug program because the individuals were eligible for participation in the federal health
15 programs. In other words, Defendants treated customers differently based on eligibility for
16 participation in the federal health programs.

17 10. Jazz, CVC, and the Specialty Pharmacies would advertise and provide marketing
18 materials to patients and prescribing physicians to influence the decision to start and obtain Jazz
19 Drugs, by informing those patients and prescribing physicians, they could obtain Jazz Drugs for
20 “free”.

21 11. Submissions of bills for payment to Medicare contractors carry an implied certification
22 that the bill is free from any claim of material falsity, including that the submission was not obtained
23 as a result of a violation of any state or federal anti-kickback statute.

24 12. Jazz’s bribes and/or kickbacks to CVC constituted violations of the Federal Anti-
25 Kickback Statute (“AKS”), thereby rendering each claim unpayable by federal healthcare programs
26 and disqualifying Jazz from receiving any payment from such programs for the Subject Drugs during
27 the course of the Scheme. Jazz’s bribes and/or kickbacks also violated several state laws, namely, (1)

1 Conn. Gen. Stat. §§ 53a-161c and 53a-161d; (2) Fla. Stat. §§ 456.054 and 817.505; (3) Mass. Gen.
2 Laws ch. 175H, § 3; (4) Mich. Comp. Laws § 752.1004; (5) Ohio Rev. Code § 3999.22; and (6) 5 R.I.
3 Gen. Laws § 548.1-3. Accordingly, these bribes and/or kickbacks constituted “unlawful activity”
4 under 18 U.S.C. § 1952(b), as bribery in violation of the laws of the United States, Connecticut,
5 Florida, Massachusetts, Michigan, Ohio, and Rhode Island. Defendants used interstate mail and wire
6 facilities with the intent to (1) distribute the proceeds from this unlawful activity, and (2) promote,
7 manage, establish, carry on, or facilitate the promotion, management, establishing, or carrying on of
8 this unlawful activity. Claims relating to these bribes and kickbacks, violating the AKS and above
9 state laws, will hereinafter be referred to as the “AKS-tainted” or “tainted” claims. Assignors and
10 Class Members were proximately harmed each time a tainted claim was submitted, under the false
11 pretense that it was a “clean” claim, and paid by the Assignors and Class Members. This caused the
12 Assignors and Class Members to not get the “benefit of their bargain” i.e., paying a claim that was
13 free from unlawful activity.

14 13. Jazz ensured that the large sums of money continuously paid to CVC improperly
15 influenced CVC’s practices. Likewise, Defendants ensured that the co-payment assistance grants—
16 paid for and facilitated by Jazz and distributed by CVC—improperly influenced patients receiving
17 and/or pharmacies dispensing Jazz Drugs.

18 14. In doing so, Defendants eliminated the effects of price sensitivity—because the
19 patients (i.e., consumers) were no longer incurring any cost—thereby eliminating price considerations
20 and barriers, thus increasing the quantity dispensed by pharmacies, and the amount of claims paid by
21 Assignors and Class Members for Jazz Drugs. The number of claims paid directly relates to damages
22 Assignors and members of the class suffered. The Co-Payment Scheme provided the illusion that
23 while the Jazz Drugs were high priced, their beneficiaries were able to afford their cost sharing
24 obligations and therefore not raise any alarms, Accordingly, with price sensitivity eliminated, the Co-
25 Payment Scheme allowed Jazz to circumvent congressional safeguards and artificially increase the
26 price of Jazz Drugs for all prescriptions to supra-competitive levels.

1 15. As a result, the Assignors and Class Members were forced, and deceived into, paying
2 tainted claims, at artificially increased prices for Jazz Drugs prescriptions, and for an increased
3 quantity of claims for Jazz Drugs. This resulted in cognizable economic damages as the Assignors
4 and Class Members paid substantially more for Jazz Drugs than they otherwise would have—but for
5 the Co-Payment Scheme.

6 16. Jazz, a sophisticated pharmaceutical manufacturer, knew that the intended victims of
7 the Scheme were the health plans Plaintiffs seek to represent. Indeed, once a patient’s cost sharing
8 obligation is paid, health plans such as the Assignors and Class Members must then pay for Jazz
9 Drugs at whatever price. *To be clear*, if a patient does not provide their cost sharing obligations (e.g.,
10 co-pay), a claim will not be submitted to the health plan and a prescription will not be dispensed from
11 a pharmacy.

12 17. Plaintiffs bring this lawsuit to redress injuries caused to the Assignors and the similarly
13 situated absent Class Members, because of Defendants’ unlawful Scheme to increase the price and
14 prescription volume of the Subject Jazz Drugs.

15 18. In April of 2019, Jazz paid \$57 million and entered into a Settlement Agreement with
16 the United States of America (“Settlement”), acting through the United States Department of Justice
17 (“DOJ”) and on behalf of the Office of Inspector General (“OIG”) of the Department of Health and
18 Human Services (“HHS”) (collectively, the “United States”) regarding the same general conduct at
19 issue in this lawsuit (*See Jazz Settlement Agreement*, attached as **Exhibit 1**). Under the terms of the
20 Jazz Settlement, Jazz paid the United States \$57 million to settle the United States’ claims that Jazz
21 violated the AKS and False Claims Act (“FCA”).

22 19. The Jazz Settlement did not address or settle damages sustained by the Assignors and
23 Class Members. The terms of the Jazz Settlement did not address the claims Plaintiffs set forth in this
24 action.

25 20. Additionally, CVC made several fraudulent and voidable transfers to Adira, in
26 violation of Va. Code Ann. §§ 55.1-400 *et seq.*

21. Adira is the de facto successor of CVC. Adira was created by and has always been operated by the very same people who operated CVC—including, but not limited to Greg Smiley, James Rock, and Bruce Packett. Adira received the remainder of CVC’s assets, including cash, investments, and valuable personal property. Adira received and, unless recently disposed of, continues to maintain all of CVC’s data including taking ownership and control of what CVC described as its “home-grown patient portal for monitoring patient and grant data—known in shorthand by previous leadership as PAMS [which] was [CVC’s] largest and most significant of assets.”⁵ As CVC’s successor, Adira is liable for CVC’s debts and liabilities.

22. As a co-conspirator to the Scheme to defraud, Adira is jointly and severally liable for the harm caused by CVC’s and Jazz’s conduct.

23. Indeed, each Defendant is jointly and severally liable for the conduct of the others, including the conduct of the conspiring Specialty Pharmacies.

24. Plaintiffs bring this lawsuit to redress the damages sustained by Assignors and Class Members as a result of Defendants’ unlawful Scheme to increase the prices and dispensed quantities of Jazz Drugs and to submit tainted claims for Jazz Drugs.

25. The improper actions alleged herein allowed Jazz to maintain supra-competitive prices by eliminating price sensitivity that would have directly benefited consumers and the public at large by forcing Jazz to price their products at market realities. Patient price sensitivity counterbalances Jazz’s desire to inflate prices for medically necessary drugs—which is why Congress relies on patient price sensitivity as a vital mechanism for combating supra-competitive pricing for Government payors. CVC’s co-payment assistance program allowed Jazz to increase the price of the Jazz Drugs regardless of the relevant market conditions by insulating Jazz from the realities of patients’ inability

⁵ It is important to note that Plaintiffs entered into a separate settlement agreement with CVC to be provided the PAMS database so Plaintiffs may provide the Court with *every* beneficiary at issue in this case; however, due to CVC materially breaching that settlement agreement by not providing access to the PAMS database, Plaintiffs are only able to provide a subset of *confirmed* claims for this Complaint that directly went through the Scheme alleged herein. Currently, Plaintiffs have a database comprised of thousands of claims relating to this case, and through discovery of the remaining data held in the exclusive possession and control of Defendants, will be able to affirmatively identify the specific claims tainted by Defendants’ scheme.

1 to afford high co-payment obligations—obligations that would have had to have been capped at a
 2 reasonable amount but-for the unlawful Scheme alleged herein. Not only did this allow Jazz to charge
 3 supra-competitive prices, but also resulted in the artificially increased volume of dispensed Jazz
 4 Drugs.⁶

5 26. Defendants used mail and wires in furtherance of their racketeering Scheme. Jazz used
 6 the wires to transmit their Corporate Contributions to CVC, which, in reality, were bribes and/or
 7 kickbacks to CVC. CVC would then transmit data using the mail and wires that it was prohibiting
 8 from sharing, allowing Jazz to perform what amounted to ROI calculations on their Corporate
 9 Contributions. Defendants would also use the mail and wire to communicate with pharmacies,
 10 including the conspiring Specialty Pharmacies, regarding, among other things, referrals and co-
 11 payments for patients prescribed Jazz Drugs. This resulted in the further use of mail and wires by
 12 pharmacies, including the conspiring Specialty Pharmacies, submitting claims for payment (along
 13 with accompanying false certifications) to Assignors and Class Members.

14 27. Defendants' conduct violated the AKS, 42 U.S.C. § 1320a-7b; the Travel Act,
 15 18 U.S.C. § 1952 ("Travel Act"); Mail Fraud, 18 U.S.C. § 1341; Wire Fraud, 18 U.S.C. § 1343; Conn.
 16 Gen. Stat. §§ 53a-161c and 53a-161d; Fla. Stat. §§ 456.054 and 817.505; Mass. Gen. Laws ch. 175H,
 17 § 3; Mich. Comp. Laws § 752.1004; Ohio Rev. Code § 3999.22; and 5 R.I. Gen. Laws § 548.1-3; and
 18 Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, ("FTCA").

19 **PARTIES**

20 **A. Plaintiffs**

21 28. Plaintiffs are companies that assist Government Healthcare Plans in detecting claims
 22 payments that are subject recoupment, either because they were conditional secondary payments or
 23 because there was fraud, mistake, or other recovery rights implicated by the payment. Pursuant to
 24 this, Plaintiffs obtained assignments from their Assignors to recover claims paid to Defendants as a
 25 result of Defendants' fraud, waste, and abuse. Assignors provide health insurance coverage, pursuant
 26 _____

27 ⁶ Defendants conducted a distinct scheme and have harmed the following putative class: (i) all insurers
 28 who paid for the cost of the Subject Jazz Drugs whose beneficiaries' co-payments were provided by
 CVC; and (ii) all insurers who paid for the cost of the Subject Jazz Drugs.

1 to Medicare Part C and Part D and Medicaid on behalf of their Enrollees. Specifically, Assignors
2 made payments for, or otherwise became financially responsible for the cost of the illegally inflated,
3 AKS-tainted, and excessively dispensed Jazz Drugs as a result of the Scheme.

4 29. Each and every cause of action identified in this Complaint was expressly assigned to
5 the named Plaintiffs. (**Exhibit 2** – Assignment Agreement).

6 MSPRC

7 30. MSPRC is a Delaware series limited liability company with its principal place of
8 business located in Coral Gables, Florida. MSPRC's limited liability company agreement provides
9 for the establishment of one or more designated Series.

10 31. MSPRC has established various designated series pursuant to Delaware law to
11 maintain various claims recovery assignments separate from other Company assets, and to account
12 for and associate certain assets with certain particular series. Pursuant to MSPRC's limited liability
13 agreement, all designated series form a part of MSPRC. MSPRC may receive assignments in the
14 name of MSPRC and further associate such assignments with a particular series or may have claims
15 assigned directly to a particular series. In either event, MSPRC will maintain the right to sue on behalf
16 of each series and pursue any and all rights, benefits, and causes of action arising from assignments
17 to a series. Any claim or suit may be brought by MSPRC in its own name, or it may elect to bring suit
18 in the name of its designated series.

19 32. MSPRC's limited liability agreement provides that any rights and benefits arising from
20 assignments to its series shall belong to MSPRC. *See Exhibit 2* – Assignment Agreement.

21 33. MSPRC has the right to seek reimbursement for payments made by SummaCare, Inc.,
22 (“SummaCare”) for which Defendants are liable due to the conduct alleged herein. *Id.*

23 34. On May 12, 2017, SummaCare irrevocably assigned all existing rights and prospective
24 rights. *Id.* To be clear, SummaCare is an Assignor in this action, *not* a Plaintiff.

25 35. From *at least* January 1, 2011, until present, SummaCare made purchases of the
26 Subject Jazz Drugs.

36. Defendants' Co-Payment Circumvention Enterprise triggered payment obligations of Assignors and Class Members. These actions caused the Assignors and Class Members to pay artificially inflated prices for the Subject Jazz Drugs. The fraudulent and anticompetitive conduct described herein directly caused damage to Assignors and the Class Members.

B. Defendants

Jazz Pharmaceutical

37. Defendant Jazz Pharmaceutical PLC is an Ireland public limited company with principal executive offices located in Dublin, Ireland. Jazz Pharmaceuticals, Inc., is a corporation organized and existing under the laws of the State of Delaware having a principal place of business in Palo Alto, California; and Jazz Pharmaceuticals Ireland, Ltd., is a corporation organized and existing under the laws of Ireland having a principal place of business in Dublin, Ireland (collectively, "Jazz"). At all relative times herein, Jazz advertised, marketed, and sold pharmaceutical products, including the Subject Jazz Drugs, throughout all states and territories in the United States, including California. Jazz derived substantial revenue related to the Subject Jazz Drugs from its business throughout each of the states and territories of the United States, including California.

38. This Court has personal jurisdiction over Jazz because Jazz's principal executive offices are located within the state of California and therefore Jazz is at home in the state.

Express Scripts

39. Defendants, Express Scripts Holdings Company, Express Scripts, Inc. and Express Scripts Specialty Distribution Services, Inc. ("Express Scripts" or "ESI") are Delaware corporations with their principal places of business located in St. Louis, Missouri.

40. Defendant Priority Healthcare Distribution, Inc. ("Priority") d/b/a CuraScript SD (collectively, "CuraScript SD"), is a wholly-owned subsidiary of Express Scripts. Priority/CuraScript SD has maintained corporate offices at 1680 Century Center Parkway, Memphis, Tennessee 38134-8827.

41. Defendant CuraScript, Inc., d/b/a CuraScript SD, f/k/a CuraScript Pharmacy, Inc., is a wholly owned subsidiary of Express Scripts. Express Scripts acquired CuraScript in January 2004.

1 Its operation was expanded when Express Scripts acquired Priority in October 2005 and combined it
2 with CuraScript. The combined Priority and CuraScript SD (collectively “CuraScript”) become one
3 of the nation’s largest specialty pharmacy and distributions companies.

4 42. CuraScript is an Indiana corporation with corporate offices located at 255 Technology
5 Park, Lake Mary, Florida 32746.

6 43. Express Scripts and CuraScripts (collectively referred to as “Express Scripts”) was, at
7 all relevant times herein, Jazz’s exclusive distributor of Xyrem, transacting and conducting business
8 throughout the nation.

9 44. Express Scripts (and its subsidiaries) provide a wide range of services, including, but
10 not limited to, PBM services, formulary placement services, Medicare Part D Sponsor Services,
11 specialty pharmacy services, co-pay assistance services, distribution services, marketing, and
12 promotion services for brand name drugs, and more. These various services, in addition to the services
13 required by nature of being publicly traded companies, necessarily require Express Scripts to abide
14 by various statutory, contractual, and fiduciary obligations that irreconcilably conflict with duties and
15 obligations owed by reason of other roles it voluntarily assumed.

16 45. At all relevant times herein, Express Scripts acted as a direct pipeline from Jazz to
17 Assignors’ beneficiaries, facilitating the direct distribution of Xyrem from Jazz to the beneficiaries’
18 homes.

19 46. Express Scripts acts as an “integrated delivery network” connecting patients to
20 manufacturers through “end-to-end distribution services.” Indeed, CuraScript is similar to FedEx, or
21 DHL, or UPS for specialty prescription drugs. CuraScript advertises that it is “recognized by the
22 manufacturing community as [] a reliable partner in the management of brands” through CuraScript’s
23 “integrated specialty services,” delivering medications directly from manufacturer to patient.

24 47. Express Scripts (and its subsidiaries) operated in all states including in the State of
25 California. Specifically, Express Scripts entered into contracts with Jazz, whose executive offices
26 were located in California.

1 Caring Voice Coalition (“CVC”)

2 48. Defendant CVC is an Idaho nonprofit corporation claiming 501(c)(3) status for tax
3 purposes, with its principal place of business in Richmond, Virginia.⁷ CVC was established in 2003
4 and operated disease funds, including the Narcolepsy and Severe Chronic Disease funds, to pay the
5 co-payments of certain patients, including Medicare patients.

6 49. This Court has personal jurisdiction over CVC because CVC’s conduct as a member
7 of the Co-Payment Circumvention Enterprise (defined below) constitutes “certain minimum contacts
8 with the forum such that the maintenance of the suit does not offend traditional conceptions of fair
9 play and substantial justice” therefore satisfying California’s Long Arm Statute. *International Shoe*
10 *Co. v. State of Washington*, 326 U.S. 310, (1945); Cal. Civ. Proc. Code § 410.10. CVC transacts its
11 affairs in the State of California. CVC further engaged in substantial and not isolated activity
12 throughout the State of California. As a result of the Co-Payment Scheme, Assignors and Class
13 Members sustained financial and economic injuries in the State of California. CVC maintains
14 systematic and continuous contacts in the State of California, and regularly transacts business in the
15 State of California. CVC purposefully availed itself of the privilege of conducting activities in the
16 State of California, thus benefiting from the protections and benefits of the law and conducting its
17 affairs in the State of California. Furthermore, at all relevant times herein, CVC contracted with Jazz.

18 Adira

19 50. Adira is a Virginia corporation claiming 501(c)(3) status for tax purposes. Adira’s
20 principal office is located at 7330 Staples Mill Road #288, Henrico, VA, 23228-4122. Adira,
21 originally incorporated under the name Facilitating Patient Health, was established in 2019 and
22 operates disease funds to pay the co-payments of certain patients, including Medicare and Medicaid
23 patients. (**Exhibit 3** – CVC & Adira Business Records).

24 51. This Court has jurisdiction over Adira because Adira is a successor company of CVC,
25 and as noted above, this Court has personal jurisdiction over CVC. *See Successor Agency to Former*
26 *Emeryville Redevelopment Agency v. Swagelok Co.*, 364 F. Supp. 3d 1061, 1074 (N.D. Cal. 2019);

27 ⁷ Pursuant to a July 31, 2019, filing with the Commonwealth of Virginia, CVC moved its principal
28 place of business to Henrico, Virginia.

1 *International Shoe Co.*, 326 U.S. at 316; Cal. Civ. Proc. Code § 410.10.

2 **JURISDICTION AND VENUE**

3 52. This Court has federal question jurisdiction pursuant to 28 U.S.C. § 1331. The causes
4 of action alleged herein arises under federal law.

5 53. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(a), because Plaintiffs
6 are completely diverse from Defendants and the amount in controversy exceeds \$75,000.00, exclusive
7 of interest and costs.

8 54. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(d), because at least
9 one member of the Class is a citizen of a state different from the Defendants and the amount in
10 controversy exceeds \$5,000,000.00, exclusive of interest and costs.

11 55. This Court has subject matter jurisdiction under 28 U.S.C. §1331, as this action alleges
12 violations of 18 U.S.C. § 1962(c) and (d).

13 56. This Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367, as the state
14 law claims are so related to the federal claims as to form part of the same case or controversy.

15 57. Venue is proper in this judicial district under 28 U.S.C. § 1391(b)(2) because a
16 substantial part of the events that gave rise to this lawsuit occurred in California. Venue is also proper
17 in this district under 18 U.S.C. § 1965(a) because Defendants transact their affairs in California.

18 **DIVISIONAL ASSIGNMENT**

19 58. This action is properly assigned to the San Jose Division of this District pursuant to
20 N.D. Cal. L.R. 3-2 because Defendant Jazz's principal place of business is in Santa Clara County,
21 which is served by the San Jose Division. Moreover, Defendant Jazz conducts substantial business in
22 Santa Clara County, which is served by this Division.

23 **STANDING**

24 59. The Assignors provide Medicare benefits to beneficiaries who have elected coverage
25 under Medicare Part C or Medicare Part D under either (i) contractual agreements, such as
26 participation and network agreements with capitation and risk sharing arrangements; or (ii) state and
27 federal laws that provide for the reimbursement of payments made by the assignor health plans.

1 60. The assignment agreements between Assignors and Plaintiffs are valid and binding
2 contracts, empowering Plaintiffs to bring and recover on the claims asserted in this lawsuit.

3 61. Plaintiffs seek recovery on behalf of each of their Assignors who paid for Jazz Drugs
4 at supra-competitive prices and paid for inflated quantities of Jazz Drugs. An explanation of the
5 representative assignment for each named Plaintiff is provided in the Appendix.

6 62. Plaintiffs seek recovery on behalf of each of their Assignors who paid for claims
7 relating to Jazz Drugs tainted by Defendants' violations of the AKS, and other state and federal
8 bribery laws, including, but not limited to: (1) Conn. Gen. Stat. §§ 53a-161c and 53a-161d; (2) Fla.
9 Stat. §§ 456.054 and 817.505; (3) Mass. Gen. Laws ch. 175H, § 3; (4) Mich. Comp. Laws § 752.1004;
10 (5) Ohio Rev. Code § 3999.22; and (6) 5 R.I. Gen. Laws § 548.1-3; and (7) Section 5 of the FTCA.

11 63. At all material times hereto, one or more Assignor(s) provided Medicare benefits to
12 MA Plan beneficiaries and one or more Assignor(s) provided Medicaid benefits to Medicaid Plan
13 beneficiaries Assignors paid supra-competitive prices for Jazz Drugs and paid for artificially inflated
14 dispensed quantities of Jazz Drugs as a result of Defendants' Scheme. Assignors also paid claims for
15 Jazz Drugs tainted by Defendants' violations of the AKS, and other state and federal bribery laws.

16 64. Defendants' Scheme triggered payment obligations for Jazz's Drugs at inflated prices
17 and induced the prescription of Jazz's Drugs.

18 65. According to Defendants' own documents, Defendants' Scheme favored and
19 encouraged dispensing of Jazz Drugs to the exclusion of generics and/or other equally effective
20 alternative treatments.

21 66. The claims paid for by Assignors involved transactions (and related events) in at least
22 the following eleven states and territories: Arizona, Connecticut, Florida, Massachusetts, Michigan,
23 New York, Nevada, Ohio, Rhode Island, Wisconsin, and Puerto Rico.

24 67. Assignors provided payment for Jazz Drugs throughout the United States, including
25 the above-referenced states and territories.

26 68. Assignor, SummaCare paid more than \$700,000 dollars in claims for the Subject Jazz
27 Drugs from *at least* January 1, 2011, through present.

69. Plaintiffs have reviewed the limited documents obtained from CVC through separate legal proceedings and have identified Enrollees that 1) received prescriptions and dispensed drugs because of the Co-Payment Circumvention Scheme; and 2) involved claims tied to direct payments from Assignor, SummaCare (and class members) to Defendants and the conspiring Specialty Pharmacies (including Express Scripts, and its affiliated entities, and BioScrip, and its affiliated entities).⁸ The Enrollees' claims that Plaintiffs put forth are just a partial list and discovery is ongoing to further ascertain the full breadth of claims funneled through CVC in furtherance of the Scheme.

70. Many of the claims paid by the representative Assignor and Class Members relate to instances where Express Scripts (or BioScrip) referred certain Enrollees to CVC, resulting in payments from Defendants to Express Scripts (and BioScrip), culminating in the use of mail and wire by the Specialty Pharmacies to submit claims and false certifications to Assignors and Class Members. This resulted in, further use of mail and wire, to transmit payment made by Assignors and Class Members directly to Defendants, including to the co-conspiring Specialty Pharmacies.

71. Jazz's exertion of control and influence over the Specialty Pharmacies and CVC pertained to, and led to, certain overt acts taken in furtherance of the conspiratorial Scheme described herein, including, but not limited to, (1) referrals of Enrollees by the Specialty Pharmacies to CVC; (2) hiring and training of employees at the Specialty Pharmacies to perform Jazz-specific roles, as instructed by Jazz; (3) implementation of policies by the Specialty Pharmacies and CVC and relating to patient assistance, in accordance with Jazz's specifications; (4) payments from CVC to the Specialty Pharmacies; (5) payments from Jazz to the Specialty Pharmacies relating to referrals made to CVC; (6) coordination of efforts between the Specialty Pharmacies and CVC to obtain "free" Jazz Drugs; and (7) marketing and advertisement materials informing patients and prescribing physicians of the opportunity to obtain "free" Jazz Drugs.

72. At all relevant times herein, Jazz also directly referred patients to CVC in order to obtain "free" Jazz Drugs, while at the same time, (1) paying CVC for each referral processed by CVC

⁸ See Confirmed Claims, attached as **Exhibit 15**.

1 and accepted into its program; and (2) paying CVC millions of dollars to ensure all patients referred
2 by Jazz and the Specialty Pharmacies receive their promised “free” Jazz Drug.

3 73. According to CVC’s records, from 2011 until 2016, Jazz paid CVC (and its managers,
4 principals, and/or agents) approximately \$24.1 million dollars.

5 74. According to investigative and other research-based findings relating to independent
6 PAPs, including CVC, (1) every \$100 million in increased donations generates approximately \$1
7 billion in increased drug sales for the manufacturer;⁹ (2) the vast majority of funds that are “donated”
8 by a pharmaceutical manufacturer are returned to it as paid transactions for supra-competitively priced
9 prescriptions that would have never been dispensed, in addition to the tax deductions also claimed by
10 the manufacturers, according to an investigation conducted by the IRS; (3) manufacturers’ use of
11 “independent” (or sham) 501(c)(3) PAPs, like CVC, eliminate price sensitivity for patients, thereby
12 decreasing usage of cheaper, therapeutically equivalent generic alternatives;¹⁰ and (4) since 2006,
13 manufacturers, including Jazz, have used “independent” PAPs, like CVC, to financially induce the
14 use of the manufacturers’ own products.¹¹

15 REGULATORY BACKGROUND

16 75. In 1965, Congress amended the Social Security Act to create the Medicare act under
17 Title XVIII of the U.S. Code. The Medicare Act created a federally funded health insurance program
18 for the nation’s elderly and disabled. The Medicare Act consists of five parts—Parts A, B, C, D, and
19 E. Parts A and B “create, describe, and regulate traditional fee-for-service, government-administered
20 Medicare.”¹² Part C outlines the Medicare Advantage program and provides that Medicare
21 beneficiaries may elect for private insurers to deliver their Medicare benefits. 42 U.S.C. §§1395w-

22 _____
23 ⁹ Reuters, *U.S. IRS probes drug company-funded patient assistance charity*, (June 29, 2017),
24 <https://www.reuters.com/article/usa-pharmaceuticals-charity/u-s-irs-probes-drug-company-funded-patient-assistance-charity-idUKL1N1JQ0UH>.

25 ¹⁰ Regence Health Policy Center, *Drug Manufacturers’ Billion-Dollar Scheme* (February 7, 2023),
26 <https://regencehpc.com/publications/drug-manufacturers-billion-dollar-scheme>.

27 ¹¹ See **Exhibit 20**, Health Affairs, Nurses, Care Delivery, Pharmaceuticals, & More 41, No. 9 (2022),
28 *Giving a Buck or Making a Buck? Donations by Pharmaceutical Manufacturers to Independent Patient Assistance Charities*.

¹² *In re Avandia Mktg. Sales Practices & Prods. Liab. Litig.*, 685 F.3d 353, 357 (3rd Cir. 2012) (citing 42 U.S.C. §§ 1395(c)-1395(i)-(5); 1395(j)-1395(w)).

21-29. Part D provides for prescription drug coverage to Medicare beneficiaries. Part E includes “Miscellaneous Provisions.”

76. Plaintiffs’ Assignors provide Medicare benefits under Parts C and D.

77. Medicare Part D coverage is a voluntary prescription drug benefit program for Medicare beneficiaries established in 2003. Medicare Part D took full effect in 2006. A beneficiary may enroll in Part D if he or she lives in the service area of a Part D plan and is entitled to Medicare benefits under Part A or enrolled under Part B.

78. Unlike Parts A and B, yet much like Medicare Part C, Medicare Part D is based on a private-market model, wherein Medicare contracts with private entities, known as Part D “sponsors.” These sponsors administer prescription drug plans, and plan sponsors must provide qualified prescription drug coverage.

79. A Part D sponsor submits a bid the year before it is to deliver Part D benefits. The bid contains a per member, per month cost estimate for providing Part D benefits to an average Medicare beneficiary in the geographic area.

80. If the Part D plan sponsor’s bid exceeds the benchmark, the enrolled beneficiary must pay the difference as part of a monthly premium. Centers for Medicare and Medicaid Services (“CMS”) then provides each Part D plan sponsor with advance monthly payments equal to the Part D plan sponsor’s standardized bid.

81. All providers and suppliers of medical services and items—including *drug manufacturers* who supply covered medications indirectly—*must enroll with Medicare* to be eligible to receive any payment for their items or services through Medicare. 42 CFR § 424.505. To enroll in Medicare, all providers and suppliers must submit an enrollment application to CMS and must “attest[] that the information submitted is accurate and that the provider or supplier is aware of, and abides by, all applicable statutes, regulations, and program instructions.” 42 CFR § 424.510(d)(3).

82. The application forms used by all providers and suppliers to enroll in Medicare includes the following attestation: “I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in . . . this application. . . . I understand that

1 payment of a claim by Medicare *is conditioned upon* the claim and the underlying transaction
 2 complying with such laws, regulations and program instructions (including, but not limited to, the
 3 Federal Anti-Kickback Statute, 42 U.S.C. section 1320a-7b(b)).”¹³ (emphasis added). The AKS was
 4 enacted to protect the “public’s confidence in the government” because the government is harmed by
 5 bribery even absent any financial harm. *See United States v. Killough*, 848 F.2d 1523, 1532 (11th Cir.
 6 1988) (citing *United States v. Miss. Valley Generating Co.*, 364 U.S. 520, 562 (1961)). Defendants
 7 are routinely held liable for abusing this trust relationship,¹⁴ and the federal government has
 8 emphasized the necessity of “closely scrutiniz[ing]” renumeration[s] relating to the recommendation
 9 of medical products” because it involves “exceptional position[s] of public trust[.]” Re: OIG Advisory
 10 Opinion No. 11-08, 2011 WL 4526111, at *4.

11 83. In addition, “in order for coverage to be available under Medicare Part D for applicable
 12 drugs of a manufacturer, the manufacturer must,” among other things, enter “into and have in effect
 13 an agreement described in § 423.2315(b).” 42 CFR § 423.2310(a). This manufacturer agreement
 14 requires that “[e]ach manufacturer . . . must comply with the requirements imposed by CMS . . . for
 15 purposes of administering the program.” 42 CFR § 423.2315. In other words, this agreement is a
 16 precondition for any of the Subject Jazz Drugs to qualify for payment by Assignors. Further, Congress
 17 has unequivocally instructed that “compliance with federal health care laws, including the [AKS], is
 18 a condition of payment by the Medicare program.” *McNutt ex rel. U.S. v. Haleyville Med. Supplies,*
 19 *Inc.*, 423 F.3d 1256, 1260 (11th Cir. 2005).

20 84. Further, when a bill is submitted to a Medicare Contractor, that bill carries an implied
 21 certification that the bill is free from material misrepresentations, including violations of the AKS
 22 and analogous state law bribery statutes referenced herein.

23 ¹³ Medicare Enrollment Application, CMS Form 855i, Available at:
 24 <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855i.pdf>. See also
 25 <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/Enrollment-Applications>.

26 ¹⁴ See, e.g., *United States v. Adebimpe*, 819 F.3d 1212, 1219 (9th Cir. 2016) (“[A]s medical equipment
 27 suppliers, [defendants] were in positions of trust with respect to Medicare.”); *United States v.*
 28 *Goldman*, 607 F. App’x 171, 176 (3d Cir. 2015) (holding that defendant who violated the AKS held
 a position of trust); *U.S. ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 389 (4th Cir. 2015) (“[False]
 claims make the administration of Medicare more difficult, and widespread fraud would undermine
 public confidence in the system.”) (cleaned up).

85. Likewise, MA Plans are required to certify compliance with the AKS and are prohibited from paying for claims that are tainted by an AKS violation or are rendered unpayable due to disqualifying conduct by the underlying provider or supplier. 42 CFR § 422.504(h)(1). Every subcontract that the MA Plan enters must also contain this certification of compliance. 42 CFR § 422.504(i).

86. MA Plans and other Part C entities play an important role in the U.S. healthcare landscape. They provide thousands of Americans with not only health insurance, but with the freedom to go into the marketplace and select the health insurance that best meets their needs. Indeed, “Congress’s goal in creating the Medicare Advantage program was to harness the power of private sector competition to stimulate experimentation and innovation.”¹⁵ In 2017, 33% of Medicare-eligible individuals got their health insurance from Medicare Advantage entities. In 2021, that figure rose to 42% and will likely rise further in the coming years.¹⁶

87. “In 2022, more than 28 million people are enrolled in a Medicare Advantage plan, accounting for nearly half or 48 percent of the eligible Medicare population, and \$427 billion (or 55%) of total federal Medicare spending (net of premiums).”¹⁷

88. Medicare Advantage entities cannot play the vital role that Congress intended if they are hamstrung by a competitive disadvantage. When Medicare Advantage entities “faithfully pursue and recover from liable third parties,” they “will have lower medical expenses and will therefore be able to provide additional benefits to their enrollees.” *In re Avandia*, 685 F.3d at 363 (quoting *Policy and Technical Changes to Medicare Advantage and the Medicare Prescription Drug Benefit Programs*, 75 Fed. Reg. 19678, 19797 (April 15, 2010)).

¹⁵ *In re Avandia Mktg. Sales Practices & Prods. Liab. Litig.*, 685 F.3d 353, 363 (3rd Cir. 2012).

¹⁶ Freed, Meredith, *Medicare Advantage in 2021: Enrollment Update and Key Trends*, June 21, 2021, Kaiser Family Foundation. Available at: <https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2021-enrollment-update-and-key-trends/>.

¹⁷ See Medicare Advantage in 2022: Enrollment Update and Key Trends: [https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-enrollment-update-and-key-trends/#:~:text=In%202022%2C%20more%20than%2028,spending%20\(net%20of%20premiums\).](https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-enrollment-update-and-key-trends/#:~:text=In%202022%2C%20more%20than%2028,spending%20(net%20of%20premiums).)

FACTUAL ALLEGATIONS

89. Jazz, the Specialty Pharmacies, and every physician who prescribed any Subject Jazz Drug submitted a Medicare Provider and/or Supplier Application. Each of these entities explicitly certified compliance with the AKS and CMS regulations and program guidelines. These entities knew that this certification and compliance was a precondition for eligibility to receive payment for any services or items to provided—directly or indirectly—to Medicare beneficiaries.

90. As an additional eligibility requirement to participate in the Part D program, Jazz entered into a contractual relationship with CMS agreeing to comply with all Medicare Program rules, including the AKS. Without this contract, none of Jazz’s drugs would have been eligible for payment under Medicare Part D.

91. “Part D enrollees with high drug costs can have difficulty affording their medications when they are in the deductible phase [and] when they reach the coverage gap—the period in which they are required to pay a larger share of total drug costs.” Congressional Research Service, *Prescription Drug Discount Coupons and Patient Assistance Programs (PAPs)*, June 15, 2017. There are two ways that pharmaceutical companies give to PAPs. First, manufacturers can establish their own PAPs. “Under this option, pharmaceutical companies give drugs directly to patients who cannot afford them or donate the drugs to a foundation that then gives them to patients. The second option is through independent charity PAPs (herein referred to as “co-payment charities”).” *See The Cloak of Social Responsibility*.

92. At all relevant times here, CVC and its successor, Adira, represented to government agencies, third-party payors, health care providers, and the public at large, that they operated legitimate independent charity PAPs, or co-payment charities, and did so in accordance with state and federal laws, as well as OIG and CMS regulations.

93. Pharmaceutical companies donate money to the co-payment charities, purportedly to help patients who cannot afford their drugs. These patients often have health insurance (usually Medicare or Medicaid) but apply to these charities to help cover all, or a portion of, their co-payment obligations.

94. There are two key differences between these two giving options. “First, companies donate drugs in option 1 and money in option 2. Second, pharmaceutical companies receive no money besides a [tax] deduction in option 1, but under option 2 they receive a [tax] deduction and money from the insurer paying the other portion of the drug costs. Thus, assistance provided by option 2 reduces out-of-pocket costs to insured patients but do[es] not reduce the price of prescription drugs to the healthcare payer. These are one-sided discounts.” *Id.* (emphasis added).

95. A small donation to a co-payment charity results in a pharmaceutical company receiving a substantial portion of the prescription’s cost from Medicare Advantage Plans, such as the Assignors.¹⁸

96. As pharmaceutical drug company “giving” to co-payment charities rises, the co-payment charity benefits as well. In fact, executives at co-payment charities are among some of the *highest paid executives* in the United States.

97. CVC is not an outlier in this phenomenon. With the increase in CVC donations, came an increase in CVC executive salaries. Pamela R. Harris, the President and Chairman of CVC received a salary of \$233,457 in 2011. By comparison, in 2015, she received a salary of \$378,200. This salary increase has a direct correlation to the amounts of donations CVC received from pharmaceutical manufacturers, like Jazz. CVC’s contributions and grants increased from \$49 million in 2011, to more than \$131 million in 2015.

98. Accordingly, in this context, pharmaceutical companies and co-payment charities have a mutually beneficial purpose—to receive donations, establish additional disease funds to cover co-payments of the pharmaceutical company’s expensive, specialty drugs, and ensure federal healthcare

¹⁸ See Michael Banigan, *A Guide to Patient Assistance Programs: What You Need to Know to Promote Patient Advocacy and Maximize Charitable Contributions.* Chronic Disease Fund Inc. (2016) (providing that pharmaceutical companies can calculate their profitability, or “charitable margin,” as a result of their donations to co-payment charities and can stand to earn 220 percent charitable margins). See *The Cloak of Social Responsibility* (explaining that example of “charitable margin” can yield a “charitable margin of 220 percent”); see also Citi Research, *The Straw that Could Break the Camel’s Back: DOJ/OIG Action on Foundation Funding Could Severely Impede Industry Returns*, May 16, 2017 (explaining that “[e]ach \$1m industry donation to a charitable foundation to enable Medicare patients Xtandi access or similar high priced drugs has the potential to generate up to \$21m for the sponsor company, **funded by the US Government.**”) (emphasis added).

programs bear the cost of these expensive, specialty drugs, so the co-payment charity can demonstrate “results” for the pharmaceutical company to justify increased donations.

99. Given these shared economic incentives, it’s no surprise that charitable assistance from co-payment charities increased from \$11 million in 2004 to nearly \$868 million in 2014. *See The Cloak of Social Responsibility*, (noting that from 2007 to 2009, during the Great Recession, pharmaceutical giving increased by nearly \$1.5 billion, whereas overall corporate giving decreased by \$1.2 billion). The chart below details total giving for certain co-payment charities, including CVC, from 2001-2014.

Table A-1 Total Giving in Dollars for Independent Charity Patient Assistance Programs (PAPs), 2001-2014

	Patient Access Network Foundation ^a	Chronic Disease Fund/ Good Days ^b	Caring Voice Coalition ^c	Healthwell Foundation ^d	Patient Services	Subtotal: Independent Charity PAPs
2001	—	—	—	—	\$2,328,611	\$2,328,611
2002	—	—	—	—	\$3,296,181	\$3,296,181
2003	—	—	—	—	\$5,118,345	\$5,118,345
2004	—	—	\$80,383	—	\$6,932,842	\$11,301,748
2005	\$7,557,312	\$5,597,689	\$5,257,803	\$15,856,793	\$15,719,269	\$49,988,866
2006	\$18,652,884	\$66,279,917	\$9,850,206	\$47,289,619	\$15,333,700	\$157,406,276
2007	\$24,880,629	\$63,551,700	\$15,816,549	\$59,391,157	\$21,467,030	\$185,107,065
2008	\$32,825,596	\$82,133,885	\$27,943,050	\$57,521,456	\$35,269,942	\$235,698,929
2009	\$37,323,252	\$136,713,152	\$37,530,583	\$71,425,660	\$29,594,995	\$312,587,592
2010	\$37,562,665	\$172,488,043	\$38,166,963	\$84,233,714	\$37,440,434	\$369,891,819
2011	\$28,379,485	\$195,647,202	\$46,827,156	\$49,521,777	\$39,983,874	\$360,359,494
2012	\$108,460,641	\$182,365,638	\$58,221,721	\$36,995,288	\$50,332,148	\$436,375,436
2013	\$174,340,174	\$194,448,004	\$67,435,466	\$31,135,498	\$60,897,475	\$528,256,117
2014	\$496,427,781	\$170,628,203	\$98,027,589	\$29,039,150	\$73,735,080	\$867,857,753

Source: ProPublica’s Nonprofit Explorer Database.
Notes: These totals come from line 13 titled “Total Grants” on Form 990, although for some entities before 2008, the totals come from line 23, part II.
^aExcluded 2004 return because it was an initial return.
^bExcluded 2004 return because it was an initial return.
^cExcluded 2002 return because it was an initial return and their reporting years run July to June.
^dExcluded 2004 return because it was an initial return.

100. The rise of co-payment charities and pharmaceutical corporate giving to such charities (with the economic incentives detailed above) is tied to the enactment of public insurance programs expanding the number of Americans with prescription drug coverage, the growth of specialty drugs, and the federal anti-kickback law.

101. First, this increased giving to co-payment charities occurred during a period in which there was a major increase in the number of Americans with prescription drug coverage as a result of the enactment of Medicare Part D and, subsequently, the passing of the Affordable Care Act in 2010 (“ACA”), which expanded Medicaid in providing prescription drug benefits. “Before these public

1 insurance expansions, federal government spending on prescription drugs was 25 percent of total
2 spending in 2005. In 2014 it was 41 percent.” *Id.*

3 102. Specialty drug prices are set by drug manufacturers with an intimate knowledge of the
4 drug market. This knowledge enables manufacturers to set supra-competitive drug prices by using
5 PAPs to circumvent beneficiary co-payment obligations, thus eliminating price sensitivity.

6 103. Second, in addition to these public insurance programs, specialty drugs (i.e., generally
7 defined as expensive prescriptions requiring extra handling or administration in treating complex
8 diseases) have contributed to the growth of co-payment charities. “In recent years, spending for
9 specialty drugs has grown faster than spending for other pharmaceuticals. Although specialty
10 medications account for only one percent of prescriptions, they account for almost a third of U.S.
11 prescription spending. For Medicare Part D, specialty drugs accounted for a quarter of a percent of
12 prescriptions in 2013 but eleven percent of total drug cost.” *Id.*

13 104. Co-payment charities allow pharmaceutical companies to manipulate price sensitivity
14 for these more expensive specialty drugs. The OIG noted that PAPs “may steer patients toward and
15 lock them into a particular manufacturer’s product, even when other equally effective and less costly
16 alternatives are available.” *Id.*

17 105. Moreover, the rise of co-payment charities was in response to federal anti-kickback
18 law. The AKS made the receipt of kickbacks, bribes, or rebates in connection with items or services
19 covered by the Medicare and Medicaid programs a crime. The AKS makes it a crime to knowingly
20 and willfully offer, pay, solicit, or receive any remuneration to induce a person to purchase or
21 recommend any good, service, or item covered under a federal health care program. *See* 42 U.S.C. §
22 1320a-7b(b). Several state laws prohibit similar conduct involving any health insurance transaction,
23 namely (1) Conn. Gen. Stat. §§ 53a-161c and 53a-161d; (2) Fla. Stat. §§ 456.054 and 817.505; (3)
24 Mass. Gen. Laws ch. 175H, § 3; (4) Mich. Comp. Laws § 752.1004; (5) Ohio Rev. Code § 3999.22;
25 and (6) 5 R.I. Gen. Laws § 548.1-3.

26 106. As it relates to PAPs, the OIG has stated that the AKS could be violated “if a donation
27 is made to a PAP to induce the PAP to recommend or arrange for the purchase of the donor’s federally
28

reimbursable items,” as well as if a PAP’s grant of financial assistance to a patient is made “to influence the patient to purchase (or induce the patient’s physician to prescribe) certain items.” *Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs*, 79 Fed. Reg. 31120, 31121 (May 30, 2014), attached as **Exhibit 4**.

107. Congress has determined that any Medicare or Medicaid claim “that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim” for purposes of the FCA. *See* 42 U.S.C. § 1320a-7b(g).

OIG Guidance for Co-Payment Charities

108. Since 2005, in advance of Medicare Part D taking full effect, the OIG has provided guidance to co-payment charities regarding compliance with applicable laws and regulations, including the AKS and the FCA. In this guidance, the OIG made clear that such charities will run afoul of those laws and regulations if they do not follow specified rules. Those rules ensure that a pharmaceutical manufacturer cannot control a co-payment charity, or receive information from such a charity, that would allow the manufacturer to link the amount it donates to additional profits from the sale of a particular drug.

109. In 2005, the OIG initially issued a special advisory bulletin on PAPs (the “2005 Special Advisory Bulletin”). The 2005 Special Advisory Bulletin provided that certain cost-sharing subsidies provided by bona fide, independent PAPs unaffiliated with drug manufacturers do not raise AKS concerns, even if the PAPs receive manufacturer contributions. *See OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70623 (Nov. 22, 2005), attached as **Exhibit 5**. The 2005 Special Advisory Bulletin also set forth factors that the OIG considers to be “fundamental” to a properly structured, independent, bona fide PAP, including the following:

- a. No drug manufacturer or donor exerts any direct or indirect influence or control over the PAP;
- b. The PAP awards assistance in a truly independent manner that severs any link between the drug manufacturer donors funding and the beneficiary;

- c. The PAP awards assistance without regard to the drug manufacturer's interests, or the beneficiary's choice of product, provider, practitioner, supplier, or Part D drug plan;
- d. The PAP provides assistance based upon a reasonable verifiable, and uniform measure of financial need that is applied in a consistent manner; and
- e. the drug manufacturer does not solicit or receive data from the PAP that would allow the manufacturer to substantiate the amount of its donations with the number of subsidized prescriptions for its products. *Id.* at 70626-27 ("Simply put, the independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries drug choices.")

110. In 2014, the OIG issued an updated bulletin raising concerns about the conduct of co-payment charities and intensifying its scrutiny of arrangements between pharmaceutical companies and co-payment charities (the "2014 Special Advisory Bulletin"). *See* 79 Fed. Reg. 31120 (May 30, 2014), attached as **Exhibit 4**. In the 2014 Special Advisory Bulletin, the OIG stated that although PAPs can provide an important safety net assistance to financially needy patients, these programs also present a risk of fraud, waste, and abuse with respect to federal health care programs if they are not sufficiently independent from donors. *Id.*

111. The OIG thereafter noted three additional areas of concern related to disease funds, eligible recipients, and the conduct of donors, and required co-payment charities to certify to the OIG that:

- a. The co-payment charity will not define its disease funds by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states.
- b. The co-payment charity will not maintain any disease fund that provides co-payment assistance for only one drug, or only the drug made or marketed by

1 one manufacturer or its affiliates; and

- 2 c. The co-payment charity will not limit its assistance to high-cost or specialty
3 drugs. Instead, the co-payment charity will make assistance available for all
4 products, including generic or bioequivalent drugs covered by Medicare or
5 other insurers, when prescribed for the treatment of the disease state(s) covered
6 by the fund.

7 *Id.*

8 112. With respect to the “conduct of donors,” the 2014 Special Advisory Bulletin reiterated
9 its prior focus [from the 2005 Special Advisory Bulletin] on co-payment charities not giving a “donor
10 any information that would enable a donor to correlate the amount or frequency of its donations with
11 the number of aid recipients who use its products or services or the volume of those products supported
12 by the PAP.” *Id.* Notably, the OIG warned that:

13 [t]he procedures described in these certifications are a critical safeguard and a material
14 fact upon which we have relied in issuing favorable advisory opinions regarding
15 Independent Charity PAPs. These opinions do not address actions by donors to
16 correlate their funding of PAPs with support for their own products. Such actions may
17 be indicative of a donor’s intent to channel its financial support to co-payments of its
18 own products, which would implicate the antikickback statute.

19 **CVC’s Growth and OIG’s Communications**

20 113. “In 2003 Congress passed the Medicare Prescription Drug, Improvement, and
21 Modernization Act of 2003, which created Medicare Part D, ‘an optional prescription drug benefit . .
22 . which went into effect in 2006.’”¹⁹

23 114. With the enactment of Part D, Congress implemented co-pay requirements as a
24 “safety-valve” against supra-competitive pricing.

25
26
27 ¹⁹ *Patient Servs., Inc. v. United States*, No. 3:18CV16, 2019 WL 267872, at *4 (E.D. Va. Jan. 18,
28 2019) (quoting Centers for Medicare & Medicaid Services, History, CMS.gov (last accessed Oct. 17,
2018), <https://www.cms.gov/About-CMS/Agency-Information/History/index.html>).

115. That same year, in 2003, CVC was founded and registered for status as a national 501(c)(3) non-profit, charitable organization aimed at providing co-payment assistance for patients with certain chronic or life-threatening diseases. CVC established certain disease funds, eventually including the Narcolepsy and *Severe* Chronic Pain Funds (at the direction of Jazz, as discussed below), which were both funded almost exclusively by Corporate Contributions (disguised as “donations) from Jazz.

116. CVC grew from receiving \$80,383 from donors in 2004 to receiving over \$131 million from donors in 2015—most of which came in the form of Corporate Contributions from a select few drug manufacturers, including Jazz.

117. With the increase in CVC donations, came an increase in CVC executive salaries. CVC’s President was Pamela R. Harris during the period Defendants carried out the Co-Payment Circumvention Scheme. Ms. Harris, along with her daughter, Samantha Harris (Ms. Samantha Harris later changed her name to Samantha Green), who served as CVC’s Vice- President, were among a handful of executives whose compensation is set forth in Part VII of CVC’s annual Form 990 Tax Filings.²⁰ Pamela R. Harris received a salary of \$234,886 in 2010. By comparison, in 2015, she received a salary of \$421,672. The rest of the executive staff at CVC saw similar pay increases. *See* CVC’s Form 990 Filings, attached as **Exhibit 6**. Samantha Harris received a salary of \$38,083 in 2010. In 2015, Samantha Harris was paid \$219,591. The same pattern is present for CVC’s director of finance, Rebecca App: her salary was \$97,786 in 2010, and rose to \$181,054 by 2015. In addition, CVC managed to add at least four more employees—none of whom were on the payroll in 2011—who were paid six-figure salaries by 2015: Taylor Scott (\$156,192), Ron Pizarz (\$140,690), Jennifer Previtera (\$124,989), and Robert Mayfield (\$115,701). These salary increases have a direct correlation to the amounts of Corporate Contributions or “bribes,” CVC received from pharmaceutical manufacturers, including Jazz.

²⁰ For the years discussed here, CVC reported based on a fiscal year of July 1 to June 30. For example, a reference to CVC’s 2011 990 (or salary paid in 2011) covers a period from July 1, 2011, to June 30, 2012.

118. CVC violated one of the most basic rules that separates legitimate co-payment charities from illegal ones—it explicitly coordinated with Jazz to steer patients towards the Subject Jazz Drugs and provided information to Jazz so that Jazz could correlate its donations with its increased profits on the sale of those drugs—and then CVC used the mail and wires to lie about it to the OIG.

119. In 2006, CVC certified to the OIG that it would comply with the requirements outlined above in the OIG’s 2005 Special Advisory Bulletin. *See* CVC 2006 Certifications to OIG, attached as **Exhibit 7**. CVC subsequently requested an advisory opinion from the OIG inquiring whether its “Proposed Arrangement” as a nonprofit, tax-exempt, charitable corporation’s proposal to provide financially needy Medicare beneficiaries with assistance and cost-sharing obligations under Medicare Part B, Medicare Part D, Medigap, and Medicare Advantage would constitute grounds for sanctions under certain federal laws, including the AKS. In response, on April 20, 2006, the OIG issued an Advisory Opinion to CVC. *Id.* The 2006 CVC Advisory Opinion noted CVC’s certification that, among other requirements, no donor had exerted or will exert “any direct or indirect influence or control” over CVC. *Id.* (“[CVC] has certified that no donor or affiliate of any donor (including, without limitation, any employee, agent, officer shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) has exerted or will exert any direct or indirect influence or control over [CVC] or any of [CVC]’s programs.”).

120. The 2006 CVC Advisory Opinion provided that upon request and as a courtesy, donors will be informed monthly of the aggregate number of patients who qualify for assistance in a category, but highlighted CVC’s certification that “the monthly data will not contain any information that enable a donor to correlate the amount or frequency of its donation with the number of subsidized prescriptions or orders for its products or the volume or medical condition of patients choosing its services.” *Id.* (“No individual patient information will be conveyed to donor, nor will any data related to the identity, amount, or nature of products or services subsidized under the Proposed Arrangement.”).

121. The OIG concluded, in part, that “[b]ased on the facts certified in [CVC’s] request for an advisory opinion and supplemental submissions” the OIG would endorse the use of CVC as a co-payment charity for certain prescribed drugs. This endorsement was reaffirmed in December 2015, following the OIG’s request that CVC certify compliance with the additional factors outlined in the 2014 Special Advisory Bulletin (the “2015 CVC Modified Advisory Opinion”), attached as **Exhibit 8**. See OIG, Adv. Op. 06-04 (Dec. 23, 2015). The 2015 CVC Modified Advisory Opinion stated that CVC had again certified compliance to each additional factor. *Id.*

Following the Enactment of Medicare Part D and the Establishment of CVC, an Ireland-Based Manufacturer Acquired the Rights to a U.S.-Made Drug, and Implemented a Scheme to Drain the Medicare Trust Fund of Millions

122. In July of 2002, prior to the enactment of Medicare Part D, the FDA approved Xyrem “as a treatment for cataplexy in patients with narcolepsy[.]”

123. On July 29, 2002, the US-based manufacturer, Orphan Medical, entered into a Services Agreement with Express Scripts, designating Express Scripts Specialty Distribution Services, Inc. (“Express Scripts” or “Specialty Pharmacy”) as its exclusive distributor.

124. In March of 2003, Jazz, an Ireland-based company, was formed.

125. On May 31, 2005, Orphan Medical and Express Scripts entered into an Amended and Restated Services Agreement (“May 2005 Agreement”). (See May 2005 Amended and Restated Services Agreement, attached as **Exhibit 9**).

126. In relevant part, the May 2005 Agreement provided the following terms,

- a. “Express Scripts Specialty Distribution Services, Inc. (“SDS”) “will facilitate the dispensing and distribution of Product, and perform certain services associated therewith;”
- b. “Exclusive Distributor. During the term of this Agreement, and for so long as the FDA mandates single central pharmacy administration of the Xyrem

Success Program,^[21] all Product sold or made available through the PAP^[22] in the Territory will be distributed exclusively through SDS pursuant to this Agreement.”

c. “Warehousing. All Product sold, or made available through the PAP, in the Territory shall be warehoused by SDS at the Facility in accordance with Exhibit A and any related SOPs and Business Rules.”

d. “PAP Orders. Subject to direction from SDS regarding available space at the Facility, Orphan shall deliver to SDS at the Facility, at Orphan’s own expense, sufficient quantities of Product to fulfill PAP Orders. The Product to be shipped by SDS pursuant to PAP Orders shall be for the account of Orphan, and title to such Product shall remain with Orphan until confirmation of the PAP order in SDS’ internal order processing system, at which time title will pass to the PAP Patient. Once NORD^[23] approves a Patient as meeting the

²¹ The May 2005 Agreement defines the “Xyrem Success Program (SM)” to mean “the pharmaceutical program for patients taking Xyrem® for which SDS shall perform the Covered Services hereunder, and which Orphan represents to be developed and implemented by, and proprietary to, Orphan.” Jazz’s use of a “single central pharmacy administration of the Xyrem Success Program” has come under recent scrutiny by government agencies and federal courts. Although Jazz represented to shareholders and the public that the FDA had mandated a “single central pharmacy administration of Xyrem” pursuant to its Risk Evaluation and Mitigation Strategy (or REMS program), it has recently been revealed that it was Jazz (and not the FDA, who opposed the idea) that insisted on a “single central pharmacy administration of the Xyrem Success Program”, where Jazz then filed a patent for this “single central pharmacy” REMS program in the FDA’s Orange Book and used that patent to keep generics off the market. *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, 555 F. Supp. 3d 829 (N.D. Cal. 2021). A federal court of appeals has recently affirmed a decision from Eastern District of Pennsylvania ordering Jazz to remove the REMS’ related patent from the Orange Book. *Jazz Pharms., Inc. v. Avadel Pharms. PLC*, 2021 WL 4860682, at *1 (D. Del. Oct. 19, 2021); (See also, FTC Amicus Brief, attached as **Exhibit 17**).

²² The May 2005 Agreement defines “PAP” to mean “the patient assistance program established by Orphan, pursuant to which SDS will provide dispensing services pursuant to the applicable SOPs and Business Rules.” The May 2005 Agreement also defines “PAP Patient” to mean “a Patient who has been approved by NORD as eligible to participate in the PAP.”

²³ As defined in the May 2005 Agreement, “NORD” stands for “the National Organization of Rare Disorders, which is responsible for determining whether individuals are eligible for participation in the PAP, based on financial criteria established by NORD, and for communicating such eligibility to SDS.” As will be discussed, after Jazz acquired the rights to Xyrem, Jazz worked with CVC to

PAP financial criteria and eligible to participate in the PAP, SDS shall treat such Patient as so eligible until SDS (a) is notified otherwise by NORD or (b) determines that such Patient does not meet (i) the criteria established by NORD for financial eligibility, or (ii) other non-financial criteria established by Orphan as set forth in the Business Rules. SDS acknowledges and agrees that any determination made by SDS pursuant to Clause (b) above may be overruled by Orphan and the affected patient shall then be considered a PAP Patient and the relevant order treated as a PAP Order hereunder. SDS shall fulfill PAP Orders as set forth in the applicable SOP and Business Rule.”

127. The May 2005 Agreement provided for an effective date through July 31, 2007, with a yearly automatic renewal thereafter.

128. The May 2005 Agreement also provided for written materials that Express Scripts would be required to sent, *at the manufacturer’s direction*, to “Patients”²⁴ as part of the “Covered Services”²⁵ to be provided by Express Scripts.

129. The May 2005 Agreement also provided, “[a]s compensation for the Covered Services performed by SDS, Orphan shall pay SDS the Fees described in Exhibit B or in an Additional Services Request Form executed by both parties. SDS shall invoice Orphan for the Fees on a monthly basis, and such Fees shall be due and payable to SDS within 30 days of the date of SDS’ invoice.”

automatically transfer all NORD-approved beneficiaries to CVC. CVC agreed to do so, because, according to CVC’s internal documents, NORD (another 501(c)(3) charity providing co-pay assistance to beneficiaries) maintained more stringent approval standards than CVC.

²⁴ The May 2005 Agreement defined “Patients” to mean “an individual who: (a) properly completes all necessary intake and Xyrem Patient Success forms (the form and content of which shall be mutually agreed upon by Orphan and SDS, and which shall comply with applicable laws and all applicable FDA requirements), as described in the relevant SOPs and Business Rules; and (b) is either deemed eligible by NORD to participate in the PAP, or is otherwise approved by SDS to receive Product.”

²⁵ The “Covered Services” to be performed by Express Scripts included, among others, (1) “Call Center Services”; (2) “Drug Information and Fulfillment Services”; (3) “Physician and Patient Registries” (4) “Xyrem Patient Assistance Program”; (5) “Dispensing Services”; (6) “Pharmacy Services”; (7) “Distribution Services” and (8) “Provision of a Xyrem program manager”.

130. The May 2005 Agreement provided that for all PAP Orders,²⁶ Jazz would set the price charged to Patients, while the price charged for Non-PAP Orders²⁷ would be set pursuant to the “sole authority” of Express Scripts.

131. The following month, in June of 2005, Jazz acquired Orphan Medical and obtained the rights to Xyrem.

132. In December of 2005, Jazz increased the price of Xyrem by approximately 6.5%.

133. In 2005, Xyrem generated \$11.2 million in revenue, which “represented primarily sales in the United States to Express Scripts.”

134. In April 2006, Jazz and Orphan Medical “received subpoenas from the United States Department of Justice in connection with the sale and marketing of Xyrem.”²⁸

135. On June 1, 2006, Jazz entered into a “Consent and Addendum to Amended and Restated Master Services Agreement” with Express Scripts (“June 2006 Agreement No. 1”, attached as **Exhibit 9**).

136. The June 2006 Agreement No. 1 provided the following relevant terms,

- a. “Jazz Pharmaceuticals acquired Orphan Medical on June 24, 2005 and desires to assume all rights and obligations of Orphan Medical under the Agreement”;

²⁶The May 2005 Agreement defined “PAP Order” to mean “a valid prescription indicating the dose, amount and strength of Product properly prescribed to a PAP Patient by a health care practitioner who is licensed to prescribe Product, and which is submitted to SDS in accordance with the relevant SOPs and Business Rules.”

²⁷ The May 2005 Agreement defined “Non-PAP Patient” to mean a Patient who is not eligible to participate in the PAP, as determined: (a) by NORD with respect to the financial eligibility of a patient; or (b) by Orphan with respect to other, non-financial criteria, and for whom SDS dispenses Product pursuant to a Non-PAP Order.”

²⁸ Although this subpoena did not relate to Jazz’s fraudulent co-payment scheme, the subpoena ultimately led to a settlement whereby Jazz agreed to pay the DOJ \$20 million for fraudulent conduct relating to Jazz’s fraudulent marketing and promoting of Xyrem. As part of the agreement, Jazz entered into a five-year Corporate Integrity Agreement (“CIA”) with the HHS-OIG, which required Jazz to adhere to certain reporting and transparency requirements to continue participating in the Medicare Part D program. Shortly after the expiration of this five-year CIA, Jazz partnered with CVC to begin a new fraudulent scheme relating to the marketing and promoting of Xyrem, as will be discussed.

b. “the parties further desire to clarify and describe in more detail the provision by ESSDS of certain Voucher Program Services (as defined in Section 2 of this Addendum) to Jazz Pharmaceuticals”; and

c. Jazz Pharmaceuticals shall pay ESSDS the fees described in Exhibit B in consideration of the performance of Voucher Program Services.”

137. The contract provided for fees to be paid by Jazz to Express Scripts for 1) Voucher Program Administrative Fees; 2) Voucher Program Dispensing Fees; 3) Voucher Program Shipment Fees.

138. On June 22, 2006, Jazz and Express Scripts entered into “Addendum No. 2 to Amended and Restated Master Services Agreement” (“June 2006 Agreement No. 2”) (*See* June 2006 Agreement No. 2, attached as **Exhibit 9**).

139. In August 2006, Jazz increased the price of Xyrem by an additional 7.4%.

140. On August 17, 2006, Jazz entered into “Addendum No 3 to Amended and Restated Master Services Agreement” (“August 2006 Agreement”) (*See* August 2006 Agreement, attached as **Exhibit 9**).

141. In 2006, Jazz generated \$29 million in sales of Xyrem, which “represented primarily sales in the United States to Express Scripts.”

142. In May 2007, Jazz increased the price of Xyrem by approximately 9%.

143. On July 16, 2007, Jazz and Express Scripts executed “Addendum No. 4 to Amended and Restated Master Services Agreement” (“July 2007 Agreement”). (*See* July 2007 Agreement, attached as **Exhibit 9**).

144. The July 2007 Agreement provided the following relevant terms:

a. “the parties are discussing ways to enhance the existing Xyrem Success Program, including the possible adoption of a specialty pharmacy HUB program, and ESSDS desires to now hire three additional full time employees in response to these discussions”;

- b. “the parties desire to include and describe in more detail the responsibilities of the three full time employees that ESSDS desires to hire and Jazz Pharmaceuticals’ payment obligation regarding same”;
- c. “ESSDS will hire a HUB Trainer, a Xyrem Account Director, and a Xyrem Operations Director to perform the FTE Services set forth in Exhibit B for Jazz Pharmaceuticals in connection with the Xyrem Success Program.”; and
- d. “Jazz Pharmaceuticals shall pay ESSDS the monthly fees described in Exhibit C in consideration of the performance of Nursing Program Services and the FTE Services... Payment of the fees for the FTE Services will commence 30 days following the hire by ESSDS of individuals to perform the FTE Services; payment for the Nursing Program Services^[29] will commence on September 1, 2007. ESSDS shall invoice Jazz Pharmaceuticals monthly. Jazz Pharmaceuticals agrees that: (1) the fees for the Xyrem® Nursing Program Services and the FTE Services shall constitute compensation for bona fide services^[30]...”

145. The July 2007 Agreement defined “FTE Services” to include the following services to be provided by full-time employees hired by Express Scripts, but paid for by Jazz:

- a. “HUB Trainer”
- i. “The Hub Trainer will provide all training relating to fulfillment and distribution of Xyrem. The Hub Trainer will dedicate [*]% of their time to training related to the Xyrem Success Program.”
- b. “Xyrem Account Director”

²⁹ The Nursing Program Services required Express Scripts to make at least four separate phone calls to any patient prescribed Xyrem, where the patient would be connected to a “Reimbursement Specialist”.

³⁰ Pursuant to 42 CFR §414.892, under Medicare regulations, “*Bona fide service fees* means fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed *on behalf of the manufacturer* that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.”

i. “The Xyrem Account Director will be designed as the single point of contact for Jazz Pharmaceuticals and will be responsible for optimizing the effectiveness of the enhanced Xyrem Success Program. The Xyrem Account Director will dedicate *100% of their time* to the Xyrem Success Program.”

c. “Xyrem Operations Director”

i. “The Xyrem Operations Director will serve as a single point of contact for the Xyrem Account Director. The Xyrem Operations Director will dedicate *100% of their time* to the Xyrem Success Program.”

ii. “All references above to the Xyrem Success Program include any enhancements subsequently made to that program, including adoption of a specialty pharmacy Hub program.”

146. On September 24, 2007, Jazz and Express Scripts entered into “Addendum No. 5 to Amended and Restated Master Services Agreement” (“September 2007 Agreement”) (*See* September 2007 Agreement, attached as **Exhibit 9**).

147. The September 2007 Agreement provided the following relevant terms,

a. “Jazz Pharmaceuticals desires ESSDS to administer a Jazz co-payment assistance pilot program for Xyrem® (the “Copayment Program”);

b. “Jazz Pharmaceuticals shall pay ESSDS a non-refundable start-up fee of \$[*] (“Start-Up Fee”). The Start-Up Fee is due and payable to ESSDS by Jazz Pharmaceuticals no later than December 7, 2007. In addition, Jazz Pharmaceuticals shall pay ESSDS a Copayment Program management fee for each month (including the months during the Copayment Program Run-Out Period) ESSDS performs Copayment Program Services (each a “Monthly Management Fee”) The Start-Up Fee and the Monthly Management Fee constitute full and complete payment for performance of the Copayment Program Services under this Addendum, other than the actual Jazz Copayment

Amounts to be paid pursuant to Section 4 hereof Jazz Pharmaceuticals agrees that: (1) the Start-Up Fee and the Monthly Management Fee for the Copayment Program Services constitutes compensation for bona fide services[.]”;

c. “Jazz Pharmaceuticals shall be responsible for portions of the copayment or coinsurance obligations of patients properly enrolled in the Copayment Program (the “Jazz Copayment Amounts”). Jazz Pharmaceuticals shall pay ESSDS the Jazz Copayment Amounts due within thirty (30) days of Jazz Pharmaceuticals’ receipt of ESSDS’s invoice pertaining thereto.”;

d. “ESSDS shall provide monthly data reports to Jazz Pharmaceuticals relating to the Copayment Program in accordance with Exhibit B attached hereto.”;

e. “The Copayment Program is designed to [*] the Xyrem Success Program. Under the Copayment Program, Jazz Pharmaceuticals will provide up to \$[*] in copayment assistance to patients properly enrolled by ESSDS in the Copayment Program for each shipment of Xyrem that occurs during the [*] period following the initial shipment.”;

f. “Patients who are enrolled in a “federal health care program” (as defined in 42 U.S.C. 1320a-7b(f)) that provides coverage for Xyrem, either as primary coverage or secondary coverage, are NOT eligible for participation in the Copayment Program.”³¹

148. By the end of 2007, Jazz generated \$39 million in revenue from Xyrem, which “represented primarily sales in the United States to Express Scripts.”

149. That year Jazz also paid Express Scripts \$1.5 million for “collecting patient registry information, providing reimbursement support, providing nursing assistance, distributing educational materials and administering a patient co-payment rebate program.”

³¹ Importantly, this September 2007 Agreement occurred while Jazz remained subject to the CIA with HHS-OIG. It was not until 2011 that Jazz contracted with CVC to create a copayment program for patients enrolled in a “federal health care program”, as discussed below.

150. On March 31, 2008, Jazz made the following representations:

a. “Under the Xyrem risk management program, Xyrem must be distributed through a single central pharmacy, Express Scripts Specialty Distribution Services, or Express Scripts...Pursuant to our agreement with Express Scripts, Express Scripts provides distribution and other customer support services to us related to the sale and marketing of Xyrem in the United States”; and

b. “Express Scripts, our sole Xyrem distributor in the United States, provides services such as collecting patient registry information, providing reimbursement support, providing nursing assistance, distributing educational materials and administering a patient co-payment rebate program.”

151. In 2008, Jazz generated \$53.8 million in revenue from Xyrem, which "primarily represent sales in the U.S. to Express Scripts Specialty Distribution Services, Inc., or Express Scripts.”

152. In February 2010, Jazz obtained a patent “covering the method for distributing Xyrem using a centralized distribution system”, where it then listed it in the Orange Book.

153. Pursuant to that exclusive agreement, Express Scripts and CuraScript submit monthly bills to Jazz for providing the following services related to Xyrem, “collecting patient registry information, providing reimbursement support, providing nursing assistance, distributing educational materials and administering a patient co-payment rebate program.”

154. In or around August of 2010, Jazz increased the price the Xyrem and extended the terms of its agreements with Express Scripts by six months, “through June 30, 2011, subject to automatic one-year extensions thereafter.”

155. In 2010, Jazz generated \$142.6 million in revenue from the sale of Xyrem, of which, only \$716,000 worth was attributed to international sales of Xyrem.

156. According to CVC’s internal meeting minutes, in or around March 2011, Jazz informed CVC that it was “looking for a co-pay program”, to which Jazz submitted a proposal to CVC for CVC to create a new fund called the Narcolepsy Fund.

157. On March 8, 2011, Jazz made the following representations:

- 1 a. “Express Scripts Specialty Distribution Services and its affiliate Curascript,
2 Inc., or Express Scripts, accounted for 79% and 77% of gross accounts
3 receivable as of December 31, 2010, and 2009, respectively.”;
- 4 b. “In 2010, sales of Xyrem to Express Scripts accounted for 84% of our net
5 product sales.”; and
- 6 c. “Under the Xyrem risk management plan, the Xyrem Success Program®,
7 Xyrem is distributed through a single central pharmacy, Express Scripts
8 Specialty Distribution Services and its affiliate Curascript, Inc., or Express
9 Scripts, with which we have an exclusive relationship”.

10 158. On or about May 1, 2011, Jazz and CVC entered a contractual relationship whereby
11 CVC would create a new co-payment program for Jazz, called the Narcolepsy Fund.

12 159. Pursuant to their arrangement, CVC and Jazz would convene every month, where CVC
13 would provide Jazz with regular status updates, regarding the use of Jazz’s Corporate Contributions
14 for patients prescribed Xyrem.

15 160. According to CVC’s internal meeting notes dated June 20, 2011, in discussing
16 Corporate Contributions from Jazz, CVC stated, “CVC officially began a financial assistance program
17 (*primarily Medicare Part D*) for Narcolepsy.”

18 161. That year, CVC approved 242 patients for Narcolepsy Financial Assistance Grants,
19 renewing 225 of those patients for co-pay assistance for the following year.

20 162. That year, CVC received \$400,000 for funding towards the Narcolepsy Fund, all of
21 which was received from Jazz.

22 163. On December 16, 2011, CVC executives called Jazz executives to provide a “status
23 update regarding patient renewal numbers and funding request for 2012.”

24 164. On December 21, 2011, CVC and Jazz had another conference call. According to
25 CVC’s internal meeting notes, the call was to “to discuss program results to-date and renewal stats.
26 Funding request for \$1M sent to [Jazz] after the conference call.”

1 165. The letter sent by CVC to Jazz requested \$1,000,000 “to continue our programs for
2 the Narcolepsy patient community.”

3 166. In 2011, Jazz paid CVC \$2.3 million in Corporate Contributions.

4 167. That year, Jazz reported an 11% increase in the sale of Xyrem, for a total of \$233.3
5 million in net product sales.

6 168. Of the \$233.3 million in Xyrem sales for 2011, only \$800,000 was received from
7 international sales of Xyrem.

8 169. On or around January 18, 2012, Jazz acquired the rights to a drug called Prialt.

9 170. “Prialt is an intrathecally administered infusion of ziconotide, approved by the FDA
10 in December 2004 for the management of severe chronic pain in patients for whom intrathecal therapy
11 is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics,
12 adjunctive therapies or intrathecal morphine. Intrathecal therapy is the delivery of the drug into the
13 intrathecal space in the spine through an infusion system comprised of a programmable infusion pump
14 and catheter.”

15 171. On January 25, 2012, CVC and Jazz had another conference call “to discuss program
16 results to-date and renewal stats.”

17 172. On or around February 16, 2012, Jazz sent a Notice of Intent to CVC “to make an
18 additional grant in the amount of one million dollars (\$1,000,000) to CVC.”

19 173. On or around February 17, 2012, Express Scripts sent an invoice to CVC for
20 approximately \$100,000 for co-pay assistance. According to internal CVC records, CVC no longer
21 had funds remaining from the “initial \$400K [from Jazz] to pay this invoice”, so CVC called Jazz to
22 request additional funding. According to internal records, Jazz instructed CVC to submit a formal
23 request in writing, even providing CVC with the exact language that should be made in the written
24 funding request.

25 174. On February 22, 2012, CVC sent a letter to Jazz “requesting grant funding for the
26 period January – March 2012 in the amount of \$1,000,000 to continue our programs for the
27 Narcolepsy patient community.”

175. Jazz then provided CVC with the requested funding to pay the \$100,000 invoice from Express Scripts relating to Xyrem co-pay assistance to Medicare Part D beneficiaries. Notably, during this time, Jazz’s Narcolepsy Fund was financed exclusively by Jazz—meaning CVC solicited funds from Jazz to cover co-payments for Jazz’s own drug (Xyrem).

176. This is but one example illustrating Defendants’ regular communications with each other to ensure Jazz was providing sufficient funds to cover co-payments for Xyrem (and Prialt).

177. By 2012, Jazz had been discussing its recent acquisition of the rights to Prialt, as well as the development of a “call center outsourced to a third-party reimbursement specialist vendor” to provide “reimbursement support” for Prialt. BioScrip was the specialty pharmacy selected by Jazz to distribute Prialt.

178. Internal CVC records indicate a “Launch Date” of September 15, 2012, for the new Severe Chronic Pain Fund created to provide co-pay assistance to Medicare Part D beneficiaries prescribed Prialt.

179. Internal CVC records identify Jazz as the only donor to the Severe Chronic Pain Fund. Other potential donors that visited CVC’s website were not aware of its existence because CVC chose not to place information about the fund online—further demonstrating the fact this fund was created and intended to be solely funded by Jazz to provide co-payment subsidies for its drug, only.

180. In 2012, CVC received approximately \$2.9 million in Corporate Contributions from Jazz. According to CVC, \$2.5 million went towards Jazz’s Narcolepsy Fund, with the remainder towards Jazz’s Severe Chronic Pain Fund.

181. In 2012, CVC received 806 new patient referrals to Jazz’s Narcolepsy Fund. Many, if not all, of those referrals came either from (1) Jazz; (2) Express Scripts, or (3) physicians provided marketing and promoting materials and communications from Defendants regarding the ability of patients to receive “free” Xyrem through CVC.

182. In 2012, CVC approved approximately 973 patients for co-pay assistance through its Narcolepsy Fund. Nearly every, if not every, co-payment grant involved Jazz’s Corporate Contributions going to Express Scripts to cover co-payment obligations relating to Xyrem.

183. Of those 973 patients, 692 were automatically approved and renewed for co-pay assistance through CVC for Xyrem in the following year. According to CVC records, an average of \$4,110 was paid by Jazz to Express Scripts for each beneficiary that received Xyrem in 2012.

184. In 2012, CVC also used Jazz's Corporate Contributions to cover the co-payment obligations of 151 patients funneled through Jazz's Severe Chronic Pain Fund.

185. For 2012, sales for Xyrem and Prialt were approximately \$405 million of Jazz's total \$586 million in sales for that year. Of the \$586 million in total sales, \$538.2 million occurred in the United States.

186. Of the \$26.4 million Jazz received in Prialt sales, at least \$6.6 million (or 25%) was paid for by Government Payors.³²

187. Of the \$378.7 million Jazz received in Xyrem sales, at least \$74 million (20%) was paid for by Government Payors.

188. On October 30, 2013, Jazz sent CVC (through the wire or mail) a Notice of Intent to pay \$175,000 to CVC "as requested to support CVC's 2014 financial assistance services to patients with Severe Chronic Pain."

189. For 2013, CVC received 755 new patient referrals towards Jazz's Narcolepsy Fund.

190. Again, during the course of this scheme, most, if not all, referrals to Jazz's Narcolepsy Fund and Severe Chronic Pain Fund came through, or at the direction of, (1) Jazz; (2) Express Scripts; (3) BioScrip; or (4) physicians provided marketing materials regarding the ability for Medicare Part D beneficiaries to receive "free" Xyrem or Prialt through CVC.

191. For 2013, CVC used Jazz funds to pay Express Scripts for the co-pay obligations of approximately 1,040 patients taking Xyrem, and approximately 400 patients taking Prialt.

192. In 2013, Jazz paid CVC approximately \$3.7 million, of which approximately \$3 million was given to Express Scripts for co-payments relating to Xyrem.

³² Information relating to the amount paid by government payors per year, per drug, is made publicly available at <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/information-on-prescription-drugs>.

193. In 2013, Government Payors paid at least \$121 million for Xyrem, and \$5.6 million for Prialt.

194. On or around January 30, 2014, Jazz sent another Notice of Intent to CVC for an additional grant of \$1,000,000 “to CVC as requested in support of CVC’s programs for the Narcolepsy community.”

195. On or around April 21, 2014, Jazz sent another Notice of Intent to CVC for an additional grant of \$2,500,000 “to CVC as requested in support of CVC’s programs for the Narcolepsy patient community.”

196. On or around June 24, 2014, Jazz sent another Notice of Intent to CVC for an additional grant of \$1,300,000 “to CVC as requested in support of CVC’s programs for the Narcolepsy patient community.”

197. On February 25, 2015, Jazz made the following representations:

- a. ***“ESSDS also provides reimbursement support to patients by coordinating insurance coverage for Xyrem, and as applicable, referring qualified patients to various patient savings or assistance programs.”*** (emphasis added);
- b. “Pursuant to our agreement, ESSDS exclusively distributes Xyrem in the United States and *provides customer support services* related to the sales and marketing of Xyrem in the United States;
- c. “In the United States.... Prialt is sold through an exclusive wholesale distributor and pharmacy, BioScrip, Inc., to medical facilities.”; and
- d. “A significant portion of our net product revenues are derived from sales of Xyrem. We sell Xyrem in the United States to a single central pharmacy, Express Scripts Specialty Distribution Services and its affiliate CuraScript, Inc., or Express Scripts.”

198. On or around March 7, 2014, CVC and Jazz entered into an amended agreement, further extending the terms of their relationship through March 7, 2017.

199. On or around April 21, 2014, Jazz sent (through the mail and wire) a Notice of Intent to CVC for an additional grant of \$2.5 million “to CVC as requested in support of CVC’s programs for the Narcolepsy patient community.”

200. As of May 29, 2014, CVC approved approximately 1,170 co-payment grants to be paid to Express Scripts for Xyrem. The average projected grant amount was \$5,000 per beneficiary.

201. In an internal CVC document dated June 4, 2014, CVC provided the following information relating to the Narcolepsy Fund:

- a. The fund contains **one donor** (Jazz);
- b. There are six manufacturers of drugs for Narcolepsy;
- c. There are seven FDA approved drugs for Narcolepsy;
- d. The total 2014 donations to the Narcolepsy Fund were \$3.5 million (all of which was provided by Jazz, the single donor).

202. In an internal CVC document dated June 4, 2014, CVC provided the following information relating to the Severe Chronic Pain Fund:

- a. The fund contains **one donor** (Jazz);
- b. There are six manufacturers of drugs for Severe Chronic Pain;
- c. There are seven FDA approved drugs for Severe Chronic Pain;
- d. The total 2014 donations to the Severe Chronic Pain Fund were \$175,000 (all of which was provided by Jazz, the single donor).

203. Put simply, because Jazz was the exclusive donor of both the Severe Chronic Pain Fund, and the Narcolepsy Fund, CVC’s solicitation was not to support the “Narcolepsy patient community” but rather a means for Defendants to directly cover any co-payment assistance for Jazz’s drugs—Xyrem and Prialta. Defendants were aware of this fact and that it was illegal.

204. On or around June 24, 2014, Jazz used the mail or wire to send CVC a Notice of Intent to make an additional grant of \$1.3 million “to CVC as requested [through the mail or wire] in support of CVC’s programs for the Narcolepsy patient community. According to the letter, \$650,000 would be paid immediately, with another \$650,000 to be paid by November 1, 2014.

1 205. In 2014, Jazz paid CVC approximately \$7.5 million in Corporate Contributions.

2 206. In 2014, CVC used Jazz's Corporate Contributions to pay Express Scripts for the co-
3 payment obligations of approximately 1,357 beneficiaries taking Xyrem.

4 207. In 2014, CVC used Jazz's Corporate Contributions to pay for the co-payment
5 obligations of approximately 629 beneficiaries taking Prialt.

6 208. Jazz saw an increase in sales of Xyrem by 37% in 2014.

7 209. According to Jazz, in 2014, it received approximately \$520.9 million from Express
8 Scripts for the sale of Xyrem in the US. Of that, according to CMS data, Government Payors paid at
9 least \$179.3 million (or 34%) for beneficiaries dispensed Xyrem.

10 210. According to Jazz, in 2014, it received approximately \$26.4 million for the sale of
11 Prialt, of which, the amount paid by Government Payors remained at approximately \$5.7 million (or
12 22%).

13 211. According to CMS data, in 2014, the average amount paid by Government Payors was
14 approximately \$70,000 per beneficiary, or \$8,200 per claim.

15 212. In December 2015, the OIG published a Modified Advisory Opinion to CVC
16 following the OIG's request that CVC certify compliance with the additional factors outlined in the
17 2014 Special Advisory Bulletin (the "2015 CVC Modified Advisory Opinion"), attached as **Exhibit**
18 **8**. See OIG, Adv. Op. 06-04 (Dec. 23, 2015). The 2015 CVC Modified Advisory Opinion stated that
19 CVC had certified compliance to each additional factor, and further that CVC had made additional
20 modifications to its current operations to address concerns it was aiding in the submission of AKS-
21 tainted claims. *Id.*

22 213. One of the tactics used by CVC to mislead the OIG (and thus enable CVC and Jazz to
23 defraud Assignors and Class Members), was through the creation of a fake "Compliance Program"
24 "to assist CVC in preventing, detecting and responding to illegal, improper and unethical conduct . .
25 . [and to] serve as a procedural framework for enhancing and monitoring compliance with applicable
26 law, regulation, the CVC Code of Conduct and organizational policies and procedures. ***The***
27 ***Compliance Program is based on . . . applicable [OIG] guidance.***" (See Summary of the CVC
28

1 Compliance Program, attached as **Exhibit 10** (emphasis added). In turn, CVC’s “Code of Conduct”
 2 purports to “describe[] the commitment that [CVC] expects of itself . . . to maintain the highest ethical
 3 standards of honesty and integrity as well as to comply with all laws and legal requirements applicable
 4 to [CVC], including [OIG] guidance for charitable patient assistance programs and CVC’s OIG
 5 Advisory Opinion 06-04, as modified, and industry guidance, including the Independent Charitable
 6 Patient Assistance Program Code of Ethics (‘IPAP Code of Ethics’).” (See CVC’s Code of Conduct,
 7 attached at **Exhibit 11**).

8 214. CVC used the wire and mail to represent to the OIG and public that it was “dedicated
 9 to the following values/ethical principles . . . [among others]”:

- 10 a. Act with honesty, integrity and objectivity, and in a manner that will merit the
 11 continued trust and confidence of patients and stakeholders.
- 12 b. Operate independently, free from the influence of CVC donors . . .
- 13 c. Comply with all federal, state, and local laws, regulations, and legal
 14 requirements applicable to CVC, including OIG guidance for charitable patient
 15 assistance programs and CVC’s OIG Advisory Opinion 06-04, as modified . . .
- 16 d. Be vigilant in the detection and prevention of potential fraud, waste or
 17 abuse . . .
- 18 e. Promptly investigate and address potential violations of applicable law,
 19 regulation, OIG guidance, CVC’s Advisory Opinion, IPAP Code of Ethics, this
 20 Code, or Company policies and procedures.

21 *Id.*

22 215. The referenced IPAP Code of Ethics that CVC committed to comply with similarly
 23 provides that co-payment charities “[o]perate under the auspices of an ongoing compliance with an
 24 organization-specific [OIG] Advisory Opinion,” and “[o]perate independently, free from the
 25 influence of donors,” which included “[r]efrain[ing] from providing donors or other entities with
 26 information that could permit the correlation of the amount or frequency of donations with the number
 27 of patients assisted by the [co-payment charity] who use a donor’s products or services or the volume
 28

1 of those products supported by the [co-payment charity].” (*See* IPAP Code of Ethics, attached at
2 **Exhibit 12**).

3 216. Jazz, CVC, and Express Scripts also used the mail and wire to send false and
4 misleading promotional material to prescribing physicians and patients representing CVC’s services
5 as an “independent” charity providing free Xyrem and Prialt.

6 217. In 2015, Jazz paid another \$7.8 million in Corporate Contributions to CVC.

7 218. In 2015, CVC used Jazz’s Corporate Contributions to pay Express Scripts for the co-
8 pay obligations relating to approximately 1,577 beneficiaries taking Xyrem.

9 219. In 2015, CVC used Jazz’s Corporate Contributions to pay for the co-pay obligations
10 relating to approximately 729 patients taking Prialt.

11 220. For 2015, the amount paid by Government Payors increased to more than \$217 million
12 for Xyrem and \$6 million for Prialt.

13 221. In February of 2016, Express Scripts reportedly received \$9.1 million in revenue from
14 co-payments, which included payments from Jazz, through CVC, to Express Scripts, pursuant to the
15 Co-Payment Scheme alleged herein.

16 222. According to internal CVC records, as of November 30, 2016, CVC held \$4.2 million
17 remaining of Jazz’s Corporate Contributions to the Narcolepsy Fund, and \$542,256 remaining of
18 Jazz’s Corporate Contributions to the Severe Chronic Pain Fund.

19 223. Similarly, CVC records show that on December 5, 2016, CVC “opened” the
20 Narcolepsy Fund, approved co-payment grants for 149 patients, and “closed” the fund that same day.

21 224. In 2016, Jazz paid \$7.4 million in Corporate Contributions to CVC.

22 225. In 2016, at the direction of Jazz, CVC used Jazz’s Corporate Contributions to pay
23 Express Scripts for the co-payment obligations of approximately 1,619 beneficiaries taking Xyrem.

24 226. In 2016, at the direction of Jazz, CVC used Jazz’s Corporate Contributions to pay the
25 co-payment obligations of approximately 738 beneficiaries taking Prialt.

227. For 2016, Government Payors³³ paid at least \$260.4 million for Xyrem, and \$6.2 million for Prialt.

228. In February 2017, Express Scripts reportedly received \$8.5 million in revenue from co-payments, which included payments from Jazz, through CVC, to Express Scripts, pursuant to the Co-Payment Scheme alleged herein.

229. Internal CVC records also reveal the following, 1) CVC used a wait list for the Narcolepsy Fund and implemented a “payor of last resort policy” which “led to some [Jazz] drugs being favored over non-donor drugs...because patients seeking assistance on non-donor drugs were referred to other organizations for assistance while patients on donor drugs were not.”; 2) CVC would place patients on a wait list “based on the particular therapy they were prescribed”; 3) “Jazz wanted the Chronic Pain Fund very narrow to limit support only to intrathecal medications, meaning the fund would mostly assist patients on Jazz’s therapy, Prialt”; and 4) CVC intentionally did not list the Chronic Pain Fund on its website.

230. In an October 2017 meeting, CVC approved a 2018 Budget of \$18.8 million, where it would pay approximately \$3 million in salaries, \$2.4 million in “professional fees”, and the remainder in alleged travel expenses, occupancy expenses, office expenses and “administrative overhead” expenses.

231. In 2017, CVC used Jazz’s Corporate Contributions to pay Express Scripts for the co-payment obligations of approximately 178 beneficiaries taking Xyrem. This is approximately 1,000 patients *less than* each of the prior years.

232. In 2017, CVC used Jazz’s Corporate Contributions to pay Express Scripts for the co-payment obligations of approximately 250 beneficiaries taking Prialt.

233. In 2017, for the first time since at least 2012 (the year CMS began releasing Drug Spending Reports), the amount paid by Government Payors for Xyrem *decreased* by approximately \$17 million.

³³ It is unclear whether CMS’s data also incorporates amounts paid by Part D Sponsors, or other governmental payors, such as Plaintiffs’ Assignors and Class Members. If not, the amount paid by Government Payors is substantially more than that reflected in CMS’s yearly reports.

1 234. The DOJ's investigation of Jazz, CVC, and Express Scripts, revealed, among other
2 things, that Defendants' coordinated efforts enabled CVC to serve as a conduit for Jazz, allowing Jazz
3 to provide subsidies to beneficiaries dispensed Xyrem and Prialt. The DOJ found that CVC falsely
4 certified compliance with OIG regulations, enabling massive, nationwide fraud against Government
5 Payors.

6 235. Because of this, in November 2017, the OIG *rescinded* its prior advisory opinions
7 issued to CVC (the "2017 CVC Rescission Letter"). See OIG, Adv. Op. 06-04 (Nov. 28, 2017),
8 attached as **Exhibit 13**. The 2017 CVC Rescission Letter was based on CVC's false and fraudulent
9 certifications and representations made through the mail and wire.

10 236. The Recission Letter stated:
11 Specifically, we have determined that, in contravention of the certifications [CVC]
12 made, [CVC]: (i) provided patient specific data to one more donors that would enable
13 the donor(s) to correlate the amount and frequency of their donations with the number
14 of subsidized prescriptions or orders for their products, and (ii) allowed donors to
15 directly or indirectly influence the identification or delineation of [CVC's] disease
16 categories."

17 *Id.*

18 237. The 2017 CVC Recission letter concluded that:
19 [CVC]'s failure to comply with these certifications materially increased the risk that
20 CVC served as a conduit for financial assistance from a drug manufacturer donor to a
21 patient, and thus increased the risk that the patients who sought assistance from [CVC]
22 would be steered to federally reimbursable drugs that the manufacturer donor sold.
23 This type of steering can harm patients and the Federal health care programs, because,
24 for example, patients may be urged to seek, and physicians may be more likely to
25 prescribe, a more expensive drug if co-payment assistance is available for that drug
26 but not for less expensive but therapeutically equivalent alternatives. In these
27 circumstances manufacturers may have greater ability to raise the prices of their drugs
28

1 while insulating patients from the immediate out-of-pocket effects of price increases,
 2 leaving Federal healthcare programs like Medicare (and the taxpayers who fund those
 3 programs) to bear the cost.

4 *Id.* (emphasis added).³⁴

5 238. Every certification submitted during the time in which the Co-Payment Scheme
 6 existed was submitted through the mail or wire and was false and misleading. Such certifications also
 7 served to further conceal the fraud that is the subject of this lawsuit.

8 239. On April 4, 2019, the DOJ issued the following press release: *Three Pharmaceutical*
 9 *Companies Agree to Pay a Total of Over \$122 Million to Resolve Allegations That They Paid*
 10 *Kickbacks Through Co-Pay Assistance Foundations.* (See DOJ Press Release, attached as **Exhibit**
 11 **14**). In relevant part, the press release (which also attached a settlement agreement between the DOJ
 12 and Jazz) stated,

13 a. “The Department of Justice today announced that three pharmaceutical
 14 companies – *Jazz Pharmaceuticals plc (Jazz)*, Lundbeck LLC (Lundbeck), and
 15 Alexion Pharmaceuticals Inc. (Alexion) – have agreed to pay a total of \$122.6
 16 million to resolve allegations that they each violated the False Claims Act by
 17 illegally paying the Medicare or Civilian Health and Medical Program
 18 (ChampVA) copays for their own products, through purportedly independent
 19 foundations that the companies used as mere conduits.”

20 b. “Pharmaceutical companies undercut a key safeguard against rising drug costs
 21 when they create assistance funds to serve as conduits for the companies to
 22 subsidize the copays of their own drugs,” said Assistant Attorney General Jody
 23 Hunt of the Department of Justice’s Civil Division. “These enforcement
 24
 25

26 ³⁴ CVC subsequently announced that in light of the 2017 CVC Rescission Letter, it would not open
 27 financial assistance for any disease fund in 2018. See [http://www.caringvoice.org/decision-2018-](http://www.caringvoice.org/decision-2018-financial-assistance)
 28 [financial-assistance](http://www.caringvoice.org/decision-2018-financial-assistance). Instead, CVC’s founder, Greg Smiley, fraudulently transferred CVC’s assets to
 another 501(c)(3) company, Defendant Adira.

1 actions make clear that the government will hold accountable drug companies
2 that directly or indirectly pay illegal kickbacks.”

3 c. “We are committed to ensuring that pharmaceutical companies do not use
4 third-party foundations to pay kickbacks masking the high prices those
5 companies charge for their drugs,” said U.S. Attorney Andrew E. Lelling.
6 “This misconduct is widespread, and enforcement will continue until
7 pharmaceutical companies stop circumventing the anti-kickback laws to
8 artificially bolster high drug prices, all at the expense of American taxpayers.”

9 d. “Jazz and Lundbeck each entered five-year corporate integrity agreements
10 (CIAs) with OIG as part of their respective settlements. The CIAs require the
11 companies to implement measures, controls, and monitoring designed to
12 promote independence from any patient assistance programs to which they
13 donate. In addition, the companies agreed to implement risk assessment
14 programs and to obtain compliance-related certifications from company
15 executives and Board members.”

16 e. “These kickback schemes harm Medicare and the public,” said Gregory E.
17 Demske, Chief Counsel to the Inspector General. “OIG CIAs, such as those
18 with Jazz and Lundbeck, are designed to reduce future risks to patients and
19 taxpayer-funded programs.”

20 f. “These settlements demonstrate the FBI’s commitment to safeguard the
21 Medicare program and ensure that patients receive treatment solely based on
22 their medical needs,” said Joseph R. Bonavolonta, Special Agent in Charge of
23 the Federal Bureau of Investigation, Boston Field Division. “Not only did these
24 companies undermine a program that was set up to assist patients in decreasing
25 the cost of their drugs, but they threatened the financial integrity of the
26 Medicare program to which we all contribute and on which we all depend.”

1 g. “Jazz sells Xyrem, a narcolepsy medication with Gamma Hydroxybutyrate
2 (GHB)—a central nervous system depressant and controlled substance—as its
3 main active ingredient. The government alleged that, in 2011, Jazz asked a
4 foundation to create a fund that would pay the copays of Xyrem Medicare
5 patients and that the foundation agreed to establish a “Narcolepsy Fund,” to
6 which Jazz became the sole donor. The government alleged that Jazz knew
7 that, although Xyrem accounted for a small share of the overall narcolepsy
8 market, the fund almost exclusively used Jazz’s donations to pay copays for
9 Xyrem and required non-Xyrem patients on competing products to obtain a
10 denial letter from another assistance plan before helping them. The government
11 further alleged that, in conjunction with establishing this fund, Jazz made
12 Medicare patients ineligible for Jazz’s free drug program and instead referred
13 Xyrem Medicare patients to the foundation, enabling Jazz to generate revenue
14 from Medicare and induce purchases of the drug, rather than continuing to
15 provide these patients with free drugs. Meanwhile, Jazz raised the price of
16 Xyrem by over 150 percent from 2011 through the end of the relevant time
17 period.”

18 h. “Jazz also sold Prialt, an injectable severe chronic pain medication. The
19 government alleged that Jazz asked the same foundation to create a fund
20 ostensibly to assist patients with the co-pays of any severe chronic pain drugs,
21 but which, in practice, almost exclusively paid Prialt Medicare copays. Shortly
22 after creating the fund, the foundation allegedly told Jazz that when severe
23 chronic pain patients seeking assistance with other drugs contacted the
24 foundation, it would refer them elsewhere. The government alleged that Jazz
25 was also aware that the fund did not appear on the foundation’s website,
26 thereby minimizing the number of non-Prialt patients seeking assistance from
27
28

1 the fund. Jazz has agreed to pay \$57 million to resolve the government's
2 allegations."

3 240. In 2022, Plaintiffs, through other litigation efforts, obtained thousands of pages of
4 documents from CVC, many of which relate to the conduct at issue in this lawsuit.

5 241. Importantly, it appears CVC has either discarded or continues to withhold many
6 documents relating to its fraudulent schemes with drug manufacturers, including Jazz.

7 242. However, in comparing Assignors' data to the limited data provided by CVC (I.e.,
8 Jazz and ESI's co-conspirator), Plaintiffs have affirmatively identified claims paid for by Assignor,
9 SummaCare, as a result of Defendants' co-payment scheme. (*See* Confirmed Claims, attached as
10 **Exhibit 15**). Meaning, SummaCare's beneficiary was dispensed the drug as a direct result of going
11 through Defendants' scheme.

12 243. These Confirmed Claims, and thousands of other unconfirmed claims, involved
13 certifications submitted by Express Scripts to Plaintiffs' Assignors, where Express Scripts certified
14 that none of the underlying claims were tainted by anti-kickback violations. Express Scripts made
15 these certifications through the mail and wire, even though Express Scripts *knew* of the falsity of those
16 certifications.

17 244. In fact, not only did Express Scripts *know* the underlying claims submitted to
18 Assignors were tainted by Defendants' anti-kickback violations, but it also participated in conduct
19 that tainted those claims.

20 245. For example, Express Scripts would routinely refer beneficiaries to CVC, knowing
21 that CVC served as a conduit for Jazz to pay the co-payment obligations of beneficiaries prescribed
22 Xyrem. Express Scripts would submit invoices to CVC for those co-payment obligations. CVC would
23 use Jazz's funds to pay those invoices to Express Scripts. Express Scripts would then use the mail or
24 wire to submit claims to Plaintiffs' Assignors and Class Members along with certifications that none
25 of the claims were tainted by AKS violations, even though Express Scripts knew that to be false.

26 246. In one documented circumstance, Express Scripts submitted a \$100,000 invoice to
27 CVC for co-payment obligations relating to Xyrem. CVC processed the invoice, but did not have
28

sufficient funds *from Jazz* to cover the invoice. Therefore, CVC contacted Jazz to request more funds to cover the invoice from Express Scripts (Jazz's exclusive distributor). In response, Jazz paid CVC, who then used those funds to pay Express Scripts. Express Scripts then used the mail and wire to submit claims to Government Payors, including Assignors and Class Members, representing that the circumstances underlying each individual claim was in compliance with state and federal laws and regulations. Express Scripts knew those certifications were false. As a result, Government Payors, including Assignors and Class Members, submitted payments directly to Express Scripts.

The Co-Payment Enterprise Permitted Jazz to Charge Supra-Competitive Prices for Its Drugs

247. As part of the Scheme, Defendants artificially increased the quantity of claims the Assignors and Class Members paid for Jazz Drugs by pushing patients away from Jazz's free drug program "which was open to other financially needy patients, even if those Medicare patients could not afford their copays for Subject Jazz Drugs. Instead, in order to generate revenue from Medicare and to induce purchases of Subject Jazz Drugs, Jazz referred such Medicare patients to the foundation, which allowed the patients' copays to be paid and resulted in claims to Medicare for the remaining cost." (See **Exhibit 14** – DOJ Release). CVC's internal documents also reveal that Jazz transitioned its patients who were receiving co-payment assistance through other PAPs over to CVC. These claims, and all claims for Jazz Drugs during the Scheme, forced Assignors and Class Members to pay for Jazz Drugs at supra-competitive prices.

248. Defendants' Co-payment Circumvention Enterprise Scheme involved at least two of Jazz's drugs: *Xyrem* and *Prialt*.

249. *Xyrem* is approved to treat both cataplexy and excessive daytime sleepiness in narcolepsy; its active ingredient is Gamma Hydroxybutyrate (GHB), a central nervous system depressant and controlled substance.

250. Jazz first acquired *Xyrem* from Orphan in 2005. At the time, a one-year supply of *Xyrem* cost about \$5,000 to \$10,000.

251. Between 2007-2014, Jazz raised the price of *Xyrem* at an alarming rate. By 2014, a one-year supply costs approximately \$62,000 to \$124,000. Specifically, the recommended dose of

Xyrem ranges from 4.5 to 9 grams, which converts to a monthly dosage range of 270 to 540. In 2007, the yearly cost of Xyrem ranged from \$6,610 to \$13,219. However, by 2014, the yearly cost from Xyrem had jumped to a range from \$62,208 to \$124,416.

252. In May of 2014, Bloomberg published a ranking of drug price increases from 2007 to 2014. Xyrem ranked first with an overall increase from 841% from 2007 to 2014. Bloomberg's data indicated the following percentage increases:

Year	Price Per mL	% Change from Previous Year
2007	\$2.04	-
2008	\$3.09	51%
2009	\$4.60	49%
2010	\$6.50	41%
2011	\$9.17	41%
2012	\$12.97	41%
2013	\$17.15	32%
2014	\$19.20	12%

253. From 2012 to 2020, the cost to Part D Sponsors for each unit of Xyrem more than tripled. In other words, an increase of more than 200% from an average per unit cost of \$10.29 in 2012 to \$30.92 in 2020.³⁵

254. While the number of Part D beneficiaries receiving Xyrem rose 35% between 2012 and 2020, the number of dosage units paid by Part D Sponsors rose more than 65% over the same period. In other words, there was, on average, a 22% increase in the number of doses per patient per year—from 3,675 in 2012, to 4,467 in 2020.

255. In all, total annual spending by Part D Plans for Xyrem increased nearly 400% between 2012 and 2020, despite the number of beneficiaries receiving Xyrem increasing by only 35%.

³⁵ The DOJ Settlement notes that “[f]rom January 1, 2011 through May 31, 2014, Jazz increased Xyrem’s list price by approximately 150%.”

256. Since 2007, Jazz has incrementally raised the price of Xyrem from \$2.04 per milliliter to \$31.21, an **increase of over 1,430% as of 2021**.³⁶

257. During the same period, inflation in the United States (measured by the Consumer Price Index) increased by approximately 31.76%, or an average annual increase of approximately 2.12%.

258. These numbers directly demonstrate egregious increases in both price and volume of Xyrem in a short span of time.

259. *Prialt* is a non-narcotic pain reliever used to treat severe chronic pain in people who cannot use or do not respond to standard pain-relieving medications. Prialt works by blocking pain signals from the nerves to the brain.

260. The DOJ alleged that Defendants illegally ran the Severe Chronic Pain Fund through the Co-payment Circumvention Enterprise until May 31, 2014. According to CMS data, the average spending per dosage unit in 2012 was \$242.50. This more than doubled the next year to \$517.63 per dosage unit. However, in 2014—once the Severe Chronic Pain Fund coordination allegedly stopped—per unit spending plummeted to \$64.66.

261. Assignors' data for their covered beneficiaries yields similar findings.

262. Jazz's ability to exponentially increase the prices of the Subject Drugs year over year would not have been possible but for the fraudulent and anticompetitive conduct of the Co-Payment Enterprise.

The DOJ Settlement

263. The DOJ prosecuted Jazz and CVC for their roles in the Scheme, which also defrauded the federal government.

264. As explained by the DOJ, from at least January 1, 2011, through May 31, 2014:

³⁶ See *Xyrem Prices, Coupons and Patient Assistance Programs*, Drugs.com, <https://www.drugs.com/price-guide/xyrem> (last updated Feb. 2, 2021); *Xyrem Dosage*, Drugs.com, <https://www.drugs.com/dosage/xyrem.html> (last updated Feb. 2, 2021) (effective dose range is 6-9 grams of sodium oxybate nightly; Xyrem solution contains 0.5 grams of sodium oxybate per milliliter).

1 Jazz made donations to CVC and **used CVC as a conduit** to pay the copay obligations
2 of Medicare patients taking the Subject Drugs. In 2011, Jazz asked CVC to create a
3 fund that would pay the copays of certain Xyrem patients, including Medicare patients.
4 CVC then agreed to establish a “Narcolepsy Fund,” and **Jazz was the sole donor to**
5 **the fund**. Xyrem accounted for a small share of the overall narcolepsy drug market.
6 Theoretically, the CVC Narcolepsy Fund could cover patients taking any narcolepsy
7 medication, but, **in practice, it almost exclusively assisted patients taking Xyrem.**
8 **Jazz donated to CVC with this understanding. Moreover, CVC disadvantaged**
9 **any patients seeking assistance for two competing narcolepsy drugs by requiring**
10 **them to obtain a denial letter from another assistance plan before being eligible**
11 **for CVC assistance.** Jazz knew or should have known that CVC favored patients
12 taking Xyrem, and disadvantaged patients taking other medications. In conjunction
13 with the establishment of CVC’s Narcolepsy Fund, **Jazz changed the eligibility**
14 **criteria for its program that provided free Xyrem to patients** who could not afford
15 it and, as a result of this change, **Medicare patients no longer qualified for the**
16 **program. Instead, Jazz directed its distribution vendor to refer any Xyrem**
17 **Medicare patients with unaffordable copays to CVC** in order for Jazz to generate
18 revenue from Medicare and to induce purchases of the drug, which resulted in claims
19 to Medicare to cover the cost of the drug.

20
21 With respect to Prialt, Jazz asked CVC to create a fund ostensibly to assist patients
22 with the co-pays of any severe chronic pain drugs, and CVC then created a “Severe
23 Chronic Pain Fund.” **In practice, this fund almost exclusively assisted patients**
24 **taking Prialt. Shortly after the creation of the fund, CVC told Jazz that, when**
25 **severe chronic pain patients seeking assistance with drugs other than Prialt**
26 **contacted CVC, CVC would refer them to another assistance program. Jazz**
27 **further knew that the CVC Severe Chronic Pain Fund would not appear on the**
28

1 **CVC website, which would result in fewer patients taking medications other than**
 2 **Prialt accessing the CVC fund.** As a result of the foregoing conduct, the United
 3 States contends that Jazz caused false claims to be submitted to Medicare.
 4 (*See Exhibit 1 Jazz Settlement Agreement*) (emphasis added)

5 265. As a result of the fraudulent and anticompetitive scheme described above, the DOJ
 6 prosecuted Jazz and CVC for their scheme to defraud the Government.

7 266. This resulted in a settlement whereby Jazz agreed to pay \$57 million dollars, plus
 8 interest, to the United States after the United States alleged that Jazz's use of CVC as a conduit
 9 violated the AKS, 42 U.S.C. § 1320a-7b and the FCA, 31 U.S.C. §§ 3729-33.

10 267. While the DOJ settlement concerned the same schemes alleged herein, the DOJ has
 11 reiterated that liability and damages from the AKS does not stem from the payment of claims by a
 12 healthcare program, but rather, as a result of a fraudulent submission of payment.

13 268. The April 3, 2019, Jazz Settlement with the United States was based on the United
 14 States' claims that Jazz's conduct violated the AKS and FCA.

15 269. The DOJ's investigation revealed that CVC did not operate as an independent charity,
 16 but instead acted as a conduit for pharmaceutical companies, including Jazz, to increase the price and
 17 sale volumes of the drugs.

18 270. With the increase in CVC donations, came an increase in CVC executive salaries.
 19 Pamela R. Harris, the President and Chairman of CVC received a salary of \$234,886 in 2011. By
 20 comparison, in 2015, she received a salary of \$378,200. By 2018, Ms. Harris' compensation increased
 21 to \$754,815. The rest of the executive staff at CVC saw similar pay increases. *See Exhibit 6* – CVC's
 22 Form 990 Filings. Pamela Harris' daughter, Samantha Harris (who later changed her name to
 23 Samantha Green), served as CVC's Vice-President. In 2011, her salary was \$38,083. In 2015,
 24 Samantha Harris was paid \$176,596. By 2018, she was being paid \$232,542 by CVC. The same
 25 pattern is present for CVC's director of finance, Rebecca App: her salary was \$97,786 in 2011,
 26 \$145,762 in 2015, and \$421,361 in 2018.

1 271. This salary increase has a direct correlation to the amounts of donations CVC received
2 from pharmaceutical manufacturers, like Jazz. CVC's contributions and grants increased from \$49
3 million in 2011, to more than \$131 million in 2015.

4 272. Accordingly, in this context, pharmaceutical companies and co-payment charities have
5 a mutually beneficial purpose—to receive donations, establish additional disease funds to cover co-
6 payments of the pharmaceutical company's expensive, specialty drugs, and ensure federal healthcare
7 programs bear the cost of these expensive, specialty drugs, so the co-payment charity can demonstrate
8 "results" for the pharmaceutical company to justify increased donations.

9 **The Impact on Plaintiffs and Class Members**

10 273. The Jazz Settlement did not redress the harm the Defendants' Scheme caused to the
11 Assignors and Class Members or settle any claim that the Assignors and Class Members have against
12 the Defendants.

13 274. Defendants' misconduct caused economic injury to the Assignors and Class Members.

14 275. Defendants' conduct eliminated price sensitivity of patients purchasing or physicians
15 prescribing Subject Jazz Drugs, which in turn enabled Jazz to raise the price of its Drugs to supra-
16 competitive prices, quickly and outside of ordinary market conditions. Health plans were left to bear
17 the cost, while CVC was able to demonstrate "results" to Jazz—if Jazz "donated" money to CVC, it
18 would make money, not only off the new "customers" but also by its ability to raise prices, and ensure
19 that the drugs were still prescribed, dispensed, and reimbursed.

20 276. Beneficiary price sensitivity works to limit the market viability of raising prices.
21 Beneficiaries on the lower end of the economic range are more sensitive to price increases and will
22 therefore seek out cheaper alternatives. As price increases, these financially constrained beneficiaries
23 will be unable to afford their cost-sharing obligations. It is well known, including by Defendants, that
24 as drugs become unaffordable, even life-critical drugs, beneficiaries will manage costs by changing
25 to cheaper products or cutting the dosage or frequency of their prescription to stretch the length of a
26 prescription or by forgoing/skipping treatment altogether for a time period. Defendants' Scheme is
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1 specifically tailored to circumvent these market constraints by funneling money directly to the
2 beneficiaries most likely to reduce their treatment because of cost.

3 277. Further, all practitioners providing services that may be paid under Medicare are
4 obligated “to assure, to the extent of [their] authority that services or items ordered or provided by
5 such practitioner . . . will be provided economically.” 42 U.S.C. § 1320c–5(a)(1); *see also* 42 U.S.C.
6 § 1320a–7(b)(6)(B) (prohibiting bills that are “substantially in excess of the needs of such patients.”).
7 However, Defendants marketed directly to prescribing physicians and pharmacies that patients could
8 get “free” Jazz drugs through CVC’s PAP.

9 278. Defendants’ conduct caused MA Plan and other health plans patients to purchase the
10 Subject Jazz Drugs;

- 11 a. Jazz routinely obtained data from CVC detailing how many patients, including
12 Medicare Advantage patients, on each Subject Jazz Drug that CVC had
13 assisted and how much CVC had spent on those patients;
- 14 b. In deciding whether and how much to donate to CVC, Jazz considered the
15 revenue it would receive from prescriptions for Medicare Advantage patients
16 who received assistance from CVC to cover their co-payments for the Subject
17 Drugs;
- 18 c. Jazz used data from CVC to confirm that Jazz’s revenue far exceeded the
19 amount of Jazz’s donations to CVC;
- 20 d. Jazz ensured that Medicare Advantage bore the cost of the Subject Jazz Drugs
21 by employing a policy of not permitting Medicare Advantage patients to
22 participate in Jazz’s free drug program (i.e., Option 1 described above), which
23 was open to other financially needy patients, even if those Medicare Advantage
24 patients could not afford their co-payments for the Subject Jazz Drugs; and
- 25 e. To generate revenue from Medicare Advantage patients prescribed the Subject
26 Jazz Drugs to CVC, which upon CVC approving coverage of patients’ co-

1 payments, triggered Plaintiffs' Assignors' obligations to cover of the Subject
2 Jazz Drugs.

3 279. Defendants' Scheme violated the AKS prohibitions on illegal remuneration by Jazz
4 bribing CVC to both (a) illegally funnel funds to certain pharmacies to induce Government payors
5 (such as Assignors and Class Members) to pay for over-priced Jazz Drugs; and (b) to illegally refer,
6 recommend, and arrange for federal healthcare program beneficiaries to receive the Jazz Drugs. 42
7 U.S.C. § 1320a–7b(b).

8 280. Defendants also violated the AKS prohibitions on making and causing to be made
9 false statements and representations by Jazz breaching its certifications to comply with the AKS, by
10 causing the prescribing physicians and dispensing pharmacies to submit legally false claims to
11 Assignors and Class Members, and by concealing and failing to disclose the illegal remunerations
12 that rendered these claims false while also receiving payment for such claims. 42 U.S.C. § 1320a–
13 7b(a); *see also Universal Health Servs., Inc. v. United States*, 579 U.S. 176 (2016).

14 281. These AKS violations were done knowingly and willfully by all Defendants. Jazz's
15 bribes to CVC were done in exchange for and to induce CVC to refer and arrange for Assignors' and
16 Class Members' beneficiaries to receive Jazz's Drugs. CVC knowingly and willfully accepted these
17 bribes for this illegal purpose and did in fact carry out this purpose by funneling Jazz's money to the
18 beneficiaries and arranged for them to receive Jazz's drugs, causing claims to be submitted to
19 Assignors and Class Members.

20 282. This endemic scheme violated the express and implied certifications by CVC and
21 Jazz—made to the OIG and CMS—to adhere to the AKS, which were explicit preconditions of
22 payment. The effects of this scheme extend to all claims for the Jazz Drugs. Therefore, all claims for
23 the Jazz Drugs generated or submitted during the course of the Scheme were disqualified from being
24 paid for by Assignors and Class Members.

25 283. But-for Defendants' conduct, Assignors and Class Members would not and could not
26 have paid for *any* of the Jazz Drugs that went through Defendants' Scheme.

1 284. Because of Defendants' Scheme, Assignors and Class Members paid for prescriptions
2 they would not have otherwise paid and there was a direct relationship between the misconduct at
3 issue here and the payments Assignors and Class Members made for Enrollees. Such payments
4 involved illegal and unpayable claims, artificially increased quantities of prescribed and/or dispensed
5 Jazz Drugs, and supra-competitive prices on the Jazz Drugs.

6 285. Defendants knew and intended that their scheme would increase the number of
7 prescriptions used by Medicare Advantage patients for the Subject Jazz Drugs.

8 286. At relevant times herein, Defendants (their agents and conspirators) actively and
9 falsely marketed to and misled health care providers, third-party payors, governmental agencies, and
10 the public, regarding the legitimacy of their Co-Payment Scheme, tainting any and all claims for the
11 Jazz Drugs submitted during the course of the Scheme.

12 287. Assignors and Class Members were the primary and intended victims of Defendants'
13 Scheme. The injury to the Assignors was a foreseeable and natural consequence of the Scheme
14 because Jazz knew that third-party payors such as the MA Plans and the Medicaid Plans would
15 directly pay for or reimburse the cost of the Jazz Drugs.

16 288. Assignors and Class Members suffered direct economic injury as a direct and
17 proximate cause of Defendants' Scheme and are therefore best suited to advance and pursue the
18 recovery of the claims asserted in this Complaint.

19 289. In fact, Assignors and Class Members are the only entities harmed by Defendants'
20 Scheme.

21 290. Indeed, wholesale distributors, specialty distributors, and/or pharmacies actually
22 benefit from the scheme as their sales increase *because the rate of abandonment decreases*, their
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1 *dispensing increases*, as well as revenue from service fees, some of which are based on a percentage
 2 of the Wholesale Acquisition Cost (“WAC”).^{37, 38}

3 291. Jazz knows or has reason to know that prescription abandonment and low medication
 4 adherence (i.e., not taking the prescription as prescribed) are serious issues in treating chronic
 5 conditions, and more importantly to Defendants, their revenue decreases.^{39, 40} High co-pay costs for
 6 patients is a major contributing factor to both abandonment and low adherence.⁴¹ Instead of lowering
 7 the cost of the Jazz Drugs to account for market realities or allowing federal healthcare program
 8 beneficiaries to access its free drug program, Jazz chose to run an illegal and lucrative scheme to force
 9 Assignors and Class Members to shoulder the burden of its greed.

10 292. Defendants had the shared goal of, among other illicit objectives, maximizing the
 11 number of sales for Jazz Drugs and growing Jazz’s co-payment assistance fund—including the
 12 Narcolepsy and Severe Chronic Disease Funds—thereby enabling CVC’s directors and officers to
 13 use the non-profit charities increased revenue to justify a surge in their own compensation and
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15 ³⁷ Prescription abandonment—when a prescription is transmitted to the pharmacy but never filled—
 16 is a major concern for both providers and drug manufacturers. Prescription abandonment is multi-
 17 faceted, but it is widely understood that high co-payments are a leading cause and lowering co-
 18 payments significantly reduces abandonment for highly effective chronic treatments. Dana P.
 19 Goldman et al., *Prescription Drug Cost Sharing: Associations with Medication and Medical*
 20 *Utilization and Spending and Health*. 298.1 *Jama* 61, 61-69 (2007). Available at
 21 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6375697/>.

22 ³⁸ Prescription abandonment causes an estimated 125,000 avoidable deaths in the U.S. annually.
 23 Regardless of whether patients and doctors are induced by PAP funds at the prescription stage, the data
 24 is clear that patients are induced by co-payment assistance at the dispensing stage. Hayden B.
 25 Bosworth et al., *Medication Adherence: A Call for Action*. 162.3 *Am Heart J*. 412 (2011). Available
 26 at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3947508/>.

27 ³⁹ Stephen Mathai et al., *Low Utilization of Prostacyclin Therapy Prior to Death Among Medicare*
 28 *Patients with Pulmonary Arterial Hypertension*, Vol. 158 *Chest J*. 4 (2020). Available at
[https://journal.chestnet.org/article/S0012-3692\(20\)34047-2/fulltext](https://journal.chestnet.org/article/S0012-3692(20)34047-2/fulltext).

⁴⁰ Duncan Grady et al. *Medication and patient factors associated with adherence to pulmonary*
hypertension targeted therapies. 2018 *Pulm Circ*. 8(1), (2018). Available at
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5731720/>. Over 6% of the study sample was below
 80% adherence over a two-year period, resulting in a significant increase in reported adverse events.
 Nisha B. Shah et al. *High rates of medication adherence in patients with pulmonary arterial*
hypertension: An integrated specialty pharmacy approach, *PLOS ONE* 14(6): e0217798, (2019).
 Available at <https://doi.org/10.1371/journal.pone.0217798>.

⁴¹ See footnotes 18 and 19, *supra*.

1 luxurious lifestyle. The Co-payment Scheme increased the number of MA Plan and Medicaid Plan
2 patients (among all healthcare programs) who were receiving co-payment assistance for Jazz Drugs
3 from Jazz's co-payment fund, triggering the Assignors' and Class Members' coverage obligations for
4 these Enrollees, eliminating price sensitivity for Jazz, and allowing Jazz to increase its revenues and
5 profits related to Jazz Drugs sales.

6 293. For Defendants, this collusive bribery/kickback Scheme was a "win-win"
7 arrangement. Jazz systematically blocked MA Plan and Medicaid Plan beneficiaries from accessing
8 Jazz's free drug program. Instead, Jazz referred those beneficiaries to CVC. Jazz directed its bribes
9 and/or kickbacks to CVC with the intent to increase MA Plan and Medicaid Plan payments or
10 reimbursements. Part of those bribes and/or kickbacks were made to CVC in order for CVC to enroll
11 patients in state and federal health care plans, while other parts were made to CVC in order for CVC
12 to provide detailed quarterly reports to Jazz regarding the Jazz Drugs.

13 294. As CVC illegally provided data and information to Jazz related to the profitability of
14 Jazz's "donations" to CVC, Jazz would couple their use of CVC with price increases of Jazz Drugs.
15 Jazz's bribes and/or kickbacks to CVC resulted in more MA Plan and Medicaid Plan patients
16 receiving co-payment assistance. This in turn eliminated price sensitivity for Jazz Drugs, resulting in
17 supra-competitive pricing and artificially inflated quantities of dispensed Jazz Drugs, which together
18 increased profits for all Defendants and their executives. And all along the way, as Jazz's drug prices
19 increased and utilization of CVC increased to mask the effects of the price increases, donations to
20 CVC continued to rise, and Defendants' executives continued to pocket more and more illicitly
21 generated profits for themselves.

22 295. Data from CMS and Assignors show how Defendants' Scheme eliminated price
23 sensitivity of patients purchasing, physicians prescribing, and pharmacies dispensing Jazz Drugs and
24 resulted in federal healthcare programs bearing the increased costs. This data reflects that Jazz
25 charged supra-competitive prices and increased the quantity of Jazz Drugs paid for by federal
26 programs while the Co-Payment Circumvention Enterprise pursued such goals through unlawful
27 means, as described herein.

296. Assignors paid more than \$700,000 dollars in claims for the Subject Jazz Drugs. While Plaintiffs can directly tie a number of Plaintiffs' beneficiaries to the scheme, information in the exclusive control of Defendants will demonstrate that a significant portion of the co-payments paid on behalf of the Assignors and Class Members were made by CVC in connection with Defendants' Co-payment Circumvention Enterprise.

297. Assignors were not privy to which financially needy patients' co-payments were being provided by Jazz's bribes and/or kickbacks to CVC. The Assignors' obligations to cover claims for the Subject Jazz Drugs only arose when covered patients satisfied their co-payment obligations and Assignors did not and could not have known that their payment obligations were caused by Defendants' misconduct.

298. Evidence suggests that most, if not all, of the pharmacies that dispensed the Jazz Drugs during the relevant time period, were aware of, participated in, and/or recklessly disregarded the fact that Jazz used CVC as a conduit in violation of the AKS, resulting in millions of co-payment revenue paid by Jazz through CVC to the pharmacies. CVC's documents reveal that CVC would pay the dispensing pharmacies directly to cover the patient's co-payment and the pharmacy would in-turn bill Assignors and Class Members for the remaining cost of the drugs.

299. Defendants' documents and disclosures clearly demonstrate that they possess information to show exactly which patients received co-payment assistance.

300. For example, CVC's Form 990 Tax Filings state in Supplemental Information to Schedule I, Part I, Line 2:

Financial grants are given when an individual specifies he/she has a disease supported by Caring Voice and he/she meets stated income guidelines. Individuals fill out an application for financial assistance which must be accompanied by a medical certification from their physician documenting their diagnosis. Grant funds are paid to third party pharmacies or insurance companies after proof is received that the patient has incurred therapy costs associated with the specific diagnosis. **Caring Voice monitors the use of grant funds for individuals using proprietary database software.**

*The database maintains all records to substantiate the amount of an individual's grant, the grantees' eligibility and payments made on the grant.*⁴²

301. CVC's Code of Conduct (adopted by CVC's Board of Directors on July 22, 2017) states that CVC will:

Maintain accurate and complete books and records, including accounting and financial data, and retain such books and records in accordance with applicable federal, state and local laws and regulations, Company's record retention policies and procedures and Company instructions.⁴³

302. As noted above, Defendants' Scheme benefited CVC and its executives. CVC's President, Pamela R. Harris saw a 221% salary increase between 2011 and 2018. Her daughter, Samantha Harris (A.K.A. Samantha Green) received a 510% salary increase as Vice-President over the same period. Similarly, Rebecca App—director of finance at CVC—received a 330% pay increase. (See CVC's Form 990 Tax filings, attached as **Exhibit 6**.)

303. The information alleged was not, and could not have been, reasonably known or discovered by Plaintiffs until at least late April 2019, when Jazz' DOJ settlement was first publicly reported.

304. In addition, Defendants intentionally and fraudulently concealed the Scheme, covering up the true nature of its payments and relationship with CVC while the payments were in fact kickbacks and/or bribes for the purpose of using CVC as conduits to effectuate its goals of artificially and deceptively inflating the drug prices and increasing the use of the drugs to increase profits at the expense of healthcare payors like Assignors and the Class Members. Defendants' concealment prevented Plaintiffs, Assignors, and the Class Members from reasonably discovering the facts underlying Defendants' Scheme which caused Assignors' and the Class Members' injuries.

305. Through their Scheme, Defendants caused pharmacies to seek reimbursement from federal health care programs for their purchases of the Subject Jazz Drugs. The act of submitting claims for reimbursement carries with it an implied certification of compliance with governing federal

⁴² See **Exhibit 6** – CVC's Form 990 Tax filings.

⁴³ See **Exhibit 12** – CVC's Code of Conduct.

1 rules that are a precondition of payment. Pharmacies submitting claims for reimbursement therefore
2 implied that the claims complied with federal law, including the AKS. Defendants thus caused
3 pharmacies to provide false certifications regarding a material representation.

4 306. However, because CVC acted as a conduit for Jazz, CVC was not an independent
5 charity and instead acted in violation of the AKS. Therefore, those certifications were false.

6 307. As a result of Defendants' collusion and use of CVC as a conduit as alleged herein,
7 Assignors and the Class Members were harmed by paying for an increased number of prescriptions
8 of the Subject Jazz Drugs throughout the United States as a direct result of the Co-payment
9 Circumvention Enterprise and unfortunately the consequence of increased pricing for those
10 prescriptions, due to Jazz recouping its "donations" to CVC, for all prescriptions of Subject Jazz
11 Drugs regardless of the charities' roles.

12 **CVC's Fraudulent Transfers to Adira**

13 308. Upon information and belief, starting in 2019, Adira joined the Co-Payment
14 Circumvention Enterprise, assumed the role of conduit from CVC, partnered with Jazz, and engaged
15 in overt acts in furtherance of the scheme to defraud Assignors and Class Members.

16 309. As stated above, in or around November of 2017, the OIG issued the 2017 CVC
17 Rescission Letter.

18 310. On February 20, 2018 (just months after the 2017 CVC Rescission Letter), CVC's
19 President and Chairman together incorporated a new 501(c)(3) charity—Facilitating Patient Health,
20 which was later renamed to Adira—to continue using the same fraudulent funds in furtherance of the
21 Scheme.

22 311. During this time, CVC was aware of, and involved in, several DOJ investigations and
23 settlements for fraudulent and illegal acts at issue in this Complaint.

24 312. On April 4, 2019, the DOJ announced that it had entered into a settlement agreement
25 with Jazz regarding its fraudulent conduct with CVC. (See **Exhibit 14** – DOJ Press Release).

26 313. A few months later, CVC publicly announced that it was discontinuing operations,
27 which was false. (See CVC December 2018 Announcement, attached as **Exhibit 16**).

1 314. Instead, CVC’s management simply transferred millions in assets to themselves,
2 through Adira, and then publicly claimed to be defunct. (See **Exhibit 18** – CVC Articles of
3 Dissolution).

4 315. In fact, between at least 2011 and 2017 Greg Smiley served as treasurer of CVC.
5 Starting sometime in 2016 or 2017, Greg Smiley became the President and CEO of CVC and held
6 that position until the end of CVC’s disillusionment. (See **Exhibits 3, 6** – CVC & Adira Business
7 Records; CVC Form 990s).

8 316. Similarly, in 2014, James Rock became a director and member of the executive team
9 at CVC. Starting in 2016, James Rock was elevated to Chairman of CVC and held that position until
10 the end of CVC’s disillusionment. (See **Exhibits 3, 6** – CVC & Adira Business Records; CVC Form
11 990s).

12 317. On February 23, 2018, (just months after the 2017 CVC Rescission Letter), CVC’s
13 President Greg Smiley and Chairman James Rock together incorporated a new purported 501(c)(3)
14 charity—Facilitating Patient Health (“FPH”), which was later renamed to Adira—to continue
15 operating some of the same disease funds that CVC was forced to close. James Rock and Greg Smiley
16 were named as two of the three founding directors. (See **Exhibits 3, 19** – CVC & Adira Business
17 Records; Adira Business Records & Form 990s).

18 318. FPH’s 2019 Annual Report (submitted February 9, 2019) names James Rock as
19 Director and Greg Smiley as Director and Chief Executive Officer.

20 319. On March 15, 2019, CVC entered into a Grant Agreement with FPH. (“CVC-FPH
21 Agreement”). Greg Smiley—who was President of both CVC and FPH at the time—signed on behalf
22 of CVC, while James Rock—who was Chairman of both CVC and FPH at the time—signed on behalf
23 of FPH.

24 320. The CVC-FPH Agreement provided that CVC would provide \$3,000,000 to FPH.

25 321. On May 6, 2019, FPH amended its articles of incorporation (signed by Greg Smiley)
26 to change the organization’s name to “Adira Foundation”, which Greg Smiley referred to as the
27 “brainchild” of people affiliated with the new CVC leadership.

1 322. On May 31, 2019, CVC entered into a “Records Transfer Agreement” with Adira,
2 where CVC would “transfer title and custody of all electronic patient records . . . as well as certain
3 other records” to CVC. The Records Transfer Agreement contains an attached “Bill of Sale” which
4 purports that, in consideration of the agreement, Adira paid CVC \$10.

5 323. Greg Smiley signed the Records Transfer Agreement on behalf of both CVC and
6 Adira. No other signatures appear on the Records Transfer Agreement. In addition to Greg Smiley
7 and James Rock, several CVC employees—including other senior management personnel—began
8 working for Adira at the same time as the transfers. For example, Lauren Ruiz was Director of Patient
9 Services at CVC from November 2011, until joining Adira in April 2019 as a Programs Manager.
10 Additionally, Bruce Packett, who served as a director at CVC for several years, including from 2017-
11 2020, has now also served on Adira’s Board of Directors since 2018.

12 324. CVC and Adira even used the same accounting firm, Meadows Urquhart Acree &
13 Cook LLP, to file their respective 2019 990 forms.

14 325. Plaintiffs are in possession of further evidence of CVC fraudulently conveying its
15 assets to Adira, and Adira taking overt acts in furtherance of the Scheme.

16 326. In fact, in July of 2019, CVC continued communicating with Jazz, informing Jazz that
17 it was continuing operations and requesting Actelion’s consent to transfer approximately \$642,443 of
18 Jazz’s funds to Adira.

19 327. Adira then began using the mail and wires to correspond with Jazz, in furtherance of
20 the Scheme.

21 328. Additionally, an internal CVC document titled “CVC Board Slides 202004” reveals
22 that CVC transferred all non-restricted and unobligated funds to Adira, noting that “\$4.0 million Total
23 Will be transferred to Adira on or before 6/30/2020.” In addition, this same document instructs that
24 CVC will transfer to Adira both cash and “safe assets earning 5+%.”

25 329. Further, several additional internal CVC documents instruct that an extensive list of
26 personal property was (or would be) given to Adira, including laptops, computer servers, software
27 licensees, office equipment, etc.

330. Greg Smiley's salary from CVC in 2018 was \$190,309. In 2019, Greg Smiley's 2019 CVC salary was \$256,066 and \$192,865 in 2020. (See **Exhibit 6** — CVC Form 990). In addition to his CVC salary, Greg Smiley was paid, by Adira, \$192,865 in 2019 and \$234,248 in 2020. (See **Exhibit 19** – Adira Business Records and Form 990s).

CLASS ALLEGATIONS

331. At all material times, the Subject Jazz Drugs—manufactured, marketed, and/or sold by Jazz—were shipped across state lines and sold to customers located both within and outside its state of manufacture.

332. During the relevant time period, in connection with the purchase and sale of the Subject Jazz Drugs, monies as well as contracts, bills, and other forms of business communication and transactions, were transmitted in continuous and uninterrupted flow across state lines.

333. During the relevant time period, various methods of communication were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants, as alleged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

334. Plaintiffs bring this action on behalf of themselves and the following classes.

Federal RICO / State RICO / State Consumer Protection Statute Class 1:

All Medicare Advantage Organizations, Medicaid Managed Care Organizations, and at-risk, first-tier, and downstream entities in the United States and its territories that from *at least* January 1, 2011, through present, pursuant to Medicare and/or Medicaid contracts offering Medicare and Medicaid benefits, provided services, purchased Subject Jazz Drugs, provided payment, reimbursement, or possess the recovery rights for some or all of the purchase price of the Subject Jazz Drugs resulting from CVC's and/or Adira's co-payment assistance. This class excludes: (a) RICO Defendants, their officers, directors, management, employees, subsidiaries, and affiliates; (b) the federal government; and (c) any judges or justices involved in this action and

any members of their immediate families.

Federal RICO / State RICO / State Consumer Protection Statute Class 2:

All self-funded, third-party payors and related entities in the United States and its territories that from *at least* January 1, 2011, through present, provided services, purchased the Subject Jazz Drugs, provided payment, reimbursement, or possess the recovery rights for some or all of the purchase price of the Subject Jazz Drugs resulting from CVC's and/or Adira's co-payment assistance. This class excludes: (a) Defendants, their officers, directors, management, employees, subsidiaries, and affiliates; (b) the federal government; and (c) any judges or justices involved in this action and any members of their immediate families.

335. Plaintiffs bring this action pursuant to Federal Rules of Civil Procedure Rule 23 both individually and on behalf of a national damages class.

336. As discussed in this Complaint, Defendants' Scheme resulted in increased sales of and inflated prices for the Subject Jazz Drugs, the cost of which were borne by Assignors and the Class Members. The damages suffered by Assignors apply to all individual Class Members (and Plaintiffs as the rightful assignees of those organizations that assigned their rights to Plaintiffs). Class action law has long recognized that, when companies engage in conduct that has uniformly harmed a large number of claimants such as Plaintiffs and other third-party payers, class resolution is an effective tool to redress the harm.

337. Assignors and the Class Members have been deprived of property and money by being caused to pay for prescriptions of the Subject Jazz Drugs due to and as a result of Defendants causing the Class Members to pay for the drugs that they otherwise would not have had to without the Defendants' Scheme and engagement in the anticompetitive and racketeering activities alleged throughout this Complaint.

1 338. The Classes, defined above, are properly brought and should be maintained as a
2 nationwide class action under Rule 23(a), satisfying the class action prerequisites of numerosity,
3 commonality, typicality, and adequacy:

4 Numerosity: There are hundreds of entities (including the organizations that assigned
5 their rights to Plaintiffs) throughout the United States whose payment for the Subject
6 Jazz Drugs were caused by Defendants' Scheme. Thus, the numerosity element for
7 class certification is met.

8
9 Commonality: Questions of law or fact are common to all members of the Classes.
10 Defendants' Scheme and racketeering activity carried out by their enterprise have a
11 common, adverse effect on all Class Members. Defendants' misconduct was directed
12 at all members of these Classes. Defendants' Scheme and racketeering activity carried
13 out by their enterprise had a common, adverse effect on all purchasers of the Subject
14 Jazz Drugs who paid for the drugs because of Defendants' Scheme. Therefore,
15 common questions of law or fact are prevalent throughout the classes, *i.e.*, whether
16 Defendants engaged in a pattern of racketeering activity and conspired to induce Class
17 Members' payment for the Subject Jazz Drugs prescriptions. Each Class Member
18 shares the same needed remedy, *i.e.*, recovery for unlawfully paid bills and lost money
19 or disgorgement of Defendants' profits as a result of Defendants' Scheme and
20 racketeering activity that caused Assignors and Class Members to pay for the Subject
21 Jazz Drugs.

22
23 Typicality: Plaintiffs' claims are typical of the claims of the Classes because their
24 claims arise from the same course of conduct by Defendants, *i.e.*, Defendants'
25 formation of their Scheme and racketeering activity unlawfully causing Assignors'
26 and Class Members' submission of bills for payment for the Subject Jazz Drugs and
27 actual payment that would otherwise not have been made but for Defendants' conduct.

1 Plaintiffs' claims are, therefore, typical of the Classes.

2
3 Adequacy: Plaintiffs will fairly and adequately represent and protect the interests of
4 the Classes. Plaintiffs' interests in vindicating these claims are shared with all
5 members of the Classes. Plaintiffs are represented by competent and experienced
6 counsel in class action litigation and have particular experience with class action
7 consumer protection and RICO litigation in the pharmaceutical industry.

8 339. The Classes are properly brought and should be maintained as a class action under
9 Rule 23(b) because a class action is the superior method for resolving these claims. Pursuant to Rule
10 23(b)(3), common issues of law and fact predominate over any questions affecting only individual
11 members of the Classes. Defendants deliberately conspired to cause Assignors to pay for the Subject
12 Jazz Drugs through the formation of their co-payment scheme that subsequently resulted in the
13 submission and payment of the Subject Jazz Drugs by Assignors and the Class Members that
14 otherwise would not have been paid.

15 340. Assignors and the Class Members paid for prescriptions of the Subject Jazz Drugs that
16 they otherwise would not have paid but for Defendants' Co-payment Enterprise and racketeering
17 activity.

18 341. Members of the Classes are so numerous that joinder is impracticable. Plaintiffs
19 believe the Class includes hundreds of thousands, if not millions, of consumers, and thousands of
20 third-party payors.

21 342. Questions of law and fact common to the Class Members predominate over questions,
22 if any, that may affect only individual class members because Defendants acted on grounds generally
23 applicable to the entire class. Such generally applicable conduct is inherent in Defendants' wrongful
24 conduct.

25 343. Additional questions of law and fact common to some or all the Classes include, but
26 are not limited to:

- a. Whether Defendants engaged in a bribery and/or kickback scheme and thereby violated the AKS, the Travel Act, and/or mail and wire fraud statutes;
- b. The effect of such bribery and/or kickback scheme on the quantities dispensed and prices of the Subject Jazz Drugs; and
- c. The quantum of overcharges paid by the Assignors and Class Members in the aggregate.

344. Class action treatment is a superior method for the fair and efficient adjudication of the controversy in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

345. Plaintiffs know of no difficulty to be encountered in this action that would preclude its maintenance as a class action.

TOLLING OF THE STATUTE OF LIMITATIONS

Fraudulent Concealment Tolling

346. The claims asserted in this Complaint have been tolled as a matter of law as Defendants took affirmative steps to conceal the wrongful conduct alleged herein including, *inter alia*, Jazz utilizing CVC as a conduit and concealing such use under the guise of “donations” to an “independent” co-payment assistance charity.

347. The claims asserted in this Complaint have been tolled as a matter of law as CVC took affirmative steps to conceal the wrongful conduct alleged herein by misleading the OIG, DOJ, health care providers, certain pharmacies, beneficiaries, third-party payors, and the general public, into believing it was operating a legitimate, legal, and independent 501(c)(3) charitable organization, when in reality, it was serving as an illegal conduit for certain manufacturers, including Jazz.

1 348. The claims asserted in this Complaint have been tolled as a matter of law as CVC and
2 Adira took affirmative steps to conceal the wrongful conduct alleged herein including, inter alia,
3 CVC's fraudulent transfers to Adira and concealing such transfers as bona fide transactions.

4 Discovery Rule Tolling

5 349. Assignors did not know, and had no reasonable way of discovering, Defendants'
6 alleged Scheme until it became public knowledge.

7 350. Within the applicable statutes of limitation, Assignors could not have discovered
8 through the exercise of reasonable diligence that Defendants were concealing the conduct alleged
9 herein.

10 351. Assignors did not discover, and did not know of, facts that would have caused a
11 reasonable person to suspect that Defendants were engaged in the alleged Scheme, nor would a
12 reasonable diligent investigation have disclosed the true facts.

13 352. Assignors did not know, and had no reasonable way of discovering, CVC's and
14 Adira's fraudulent and/or voidable transfers.

15 353. Within the applicable statutes of limitation, Assignors could not have discovered
16 through the exercise of reasonable diligence that CVC and Adira were concealing their conduct
17 alleged herein. The Assignors did not discover, and did not know of, facts that would have caused a
18 reasonable person to suspect that CVC and Adira were fraudulently transferring assets, nor would a
19 reasonable diligent investigation have disclosed the true facts.

20 Equitable Tolling

21 354. Defendants were under a continuous duty to disclose to Assignors and Class Members
22 the existence and true nature of the Co-payment Circumvention Enterprise, including the subsequent
23 obligations for payment triggered by Defendant's misconduct.

24 355. The existence of Defendants' Scheme was a material fact, and Defendants concealed
25 its existence and misrepresented that they were in compliance with federal regulations, including the
26 FCA and AKS. When Defendants made these misrepresentations and concealed their Scheme, they
27 had knowledge of the facts surrounding the Scheme's existence. Defendants concealed the Scheme
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1 and made misrepresentations about it with the intent that Assignors and Class Members would rely
 2 on said misrepresentations and would pay for the Jazz Drugs. As a direct result of Defendants’
 3 Scheme, Assignors and the Class Members reasonably relied and acted upon these misrepresentations
 4 and were misled into paying for the Jazz Drugs. *See Safe Env’t of Am., Inc. v. Emps. Ins. of Wausau*,
 5 278 F. Supp. 2d 121, 126–27 (D. Mass. 2003).

6 356. Based on the foregoing, Defendants are estopped from relying on any statutes of
 7 limitations in defense of this action and all equitable principles of tolling should apply.

8 **CLAIMS FOR RELIEF**

9 **FIRST CLAIM OF RELIEF**

10 **Violation of 18 U.S.C. § 1962(c) Through the Use of the Co-Payment Charity Scheme**

11 *Against All Defendants*

12 357. Plaintiffs re-allege and incorporate by reference paragraphs 1-356 of this Complaint
 13 as if fully set forth herein.

14 358. At all relevant times, Defendants were “persons” under 18 U.S.C. § 1961(3) who
 15 conducted the affairs of the enterprise through the pattern of racketeering activity detailed throughout
 16 this Complaint in violation of 18 U.S.C. § 1962(c).

17 359. Section 1962(c) makes it “unlawful for any person employed by or associated with
 18 any enterprise engaged in, or the activities of which affect, interstate or foreign commerce to conduct
 19 or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of
 20 racketeering activity.” 18 U.S.C. § 1962(c).

21 360. Section 1964(c) provides that “any person injured in his business or property by reason
 22 of a violation of section 1962 of this chapter may sue therefor in any appropriate United States district
 23 court and shall recover threefold the damages he sustains and the cost of the suit, including a
 24 reasonable attorney’s fee.” The elements of a RICO claim under § 1964(c) pursuant to a violation of
 25 § 1962(c) are: (i) conduct; (ii) of an enterprise; (iii) through a pattern of; (iv) racketeering activity.

1 ***Description of the Co-Payment Circumvention Enterprise***

2 361. RICO defines an enterprise as “any individual, partnership, corporation, association,
3 or other legal entity, and any union group or individuals associated in fact although not a legal entity.”
4 18 U.S.C. § 1961(4).

5 362. Under 18 U.S.C. § 1961(4), a RICO “Enterprise” may be an association-in-fact that,
6 although it has no formal structure, has (i) a common purpose, (ii) relationships among those
7 associated with the enterprise, and (iii) longevity sufficient to pursue the enterprises’ purpose.

8 363. The Co-Payment Circumvention Enterprise is an association-in-fact enterprise within
9 the meaning of 18 U.S.C. § 1961(4), consisting of Defendants Jazz, CVC, and Adira, including their
10 directors, officers, employees, and agents.

11 364. The Co-Payment Circumvention Enterprise functioned as an ongoing and continuing
12 unit. The Co-Payment Circumvention Enterprise was created and/or used as a tool to effectuate a
13 pattern of racketeering activity. Each of the Enterprise participants is a “person” distinct from the
14 Enterprise.

15 365. Defendants’ common purposes were accomplished by, among other things, (1)
16 growing CVC’s fund and CVC’s executive compensation; (2) eliminating price sensitivity for patients
17 and health care providers; (3) misleading government agencies, third-party payors, health care
18 providers, and beneficiaries regarding the legitimacy of CVC’s operations and its conduct; (4)
19 funneling patients towards and then away from Jazz’s free drug program; (5) applying to Medicare
20 and Medicaid programs on behalf of beneficiaries; and (6) violating OIG regulations and providing
21 data to allow Jazz to conduct continuous ROI calculations, all of which resulted in the unlawful
22 depletion of state and federal dollars, increased the number of patients who had their drugs purchased
23 by Assignors and Class Members, and increased the personal gains received by Defendants’
24 executives through the payment of AKS-tainted claims and drugs at supra-competitive prices.

25 366. By funneling and steering people into CVC’s fund and applying for and obtaining state
26 and federal coverage for individuals, the Co-payment Circumvention Enterprise increased Jazz’s
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1 number of covered “customers,” thereby triggering the Assignors’ and Class Members’ coverage
2 obligations for their Enrollees and eliminating price sensitivity to the Jazz Drugs.

3 367. Defendants received substantial revenue from participating in the Co-Payment
4 Circumvention Enterprise. Such revenue was exponentially greater than it would have been in the
5 absence of the Scheme.

6 368. Each portion of the Co-Payment Circumvention Enterprise benefitted as intended from
7 the existence of the other parts.

8 369. The Co-Payment Circumvention Enterprise has a systemic linkage because there are
9 contractual relationships, financial ties, and continuing coordination of activities between each
10 Defendant.

11 370. There were interpersonal relationships between those associated with the Co-payment
12 Circumvention Enterprise. This includes relationships: (1) among CVC’s officers, agent, and
13 directors and relationships among Jazz’s officers, directors, principals, and agents; (2) among CVC
14 and Jazz; (3) among CVC’s officers, agents, and directors and Adira’s officers, agents, and directors;
15 and (4) among Jazz’s officers, directors, principals, and agents, and Adira’s officers, agents, and
16 directors. This is evidenced by, among other things, the routine communications (through the U.S.
17 Mail and Wire) between Defendants to enable execution of the Scheme. For example, by sharing data
18 with Jazz (in exchange for bribes and/or kickbacks), CVC enabled Jazz to track and monitor its
19 “donations” to ensure that its payments achieved their proper purpose of paying co-pays only for
20 patients receiving the Jazz Drugs, thereby substantially depleting state and federal funds and
21 increasing profits for Jazz.

22 371. The OIG explicitly warned CVC not to send pharmaceutical manufacturers this
23 information because doing so would violate the AKS and FCA, and CVC certified its understanding
24 and compliance with the OIG’s warnings. But Defendants participated in this conduct anyway. Jazz
25 settled the DOJ’s AKS and FCA claims for \$57 million for the harm caused to the United States by
26 the Scheme.

1 372. The Co-payment Circumvention Enterprise had the longevity sufficient to permit its
2 associates to pursue the enterprise's purpose. The Scheme continued for *at least* four years, during
3 which time its purposes were pursued. CVC grew its fund for the Jazz Drugs as Jazz increased its
4 annual bribes and/or kickbacks disguised as "donations" to CVC. During the same period,
5 Defendants' officers and directors increased their annual compensation, year over year.

6 373. Jazz carried out its business activities both with and without CVC. Similarly, CVC
7 operated other funds without Jazz. The Scheme thus did not involve parallel conduct because
8 Defendants participate in transactions with co-payment charities that do not result in violations of the
9 AKS, FCA, RICO, Consumer Protection Laws, OIG regulations, or other state and federal laws.

10 ***Conduct of the Enterprise's Affairs***

11 374. Each Defendant conducted or participated in, either directly or indirectly, the conduct
12 of the Co-payment Circumvention Enterprise's affairs. Each Defendant was part of the Co-payment
13 Circumvention Enterprise and each operated and managed the Co-payment Circumvention
14 Enterprise. Such participation included, but is not limited to: (1) CVC managing, collecting, and
15 sharing data (through the U.S. mail and wire facilities) with Jazz so that Jazz could effectively conduct
16 ROI analyses on the amounts of "donations" to CVC's Narcolepsy and Severe Chronic Disease
17 Funds; (2) Jazz providing bribes and/or kickbacks, disguised as donations, to CVC so the payment
18 obligations of the Assignors and Class Members would be triggered; (3) CVC and Jazz steered and
19 funneled the Jazz Drugs patients to CVC's Narcolepsy and Severe Chronic Disease Funds; and (4)
20 Adira assuming CVC's role and enabling the continuation of the Scheme after CVC's fraudulent
21 operations were covered by the DOJ, stripping CVC of its ability to continue operating as a 501(c)(3)
22 charity.

23 375. At all relevant times, each Defendant had been aware of the Co-Payment
24 Circumvention Enterprise's conduct and was a knowing and willing participant in the racketeering
25 conduct of the Enterprise.

26 ***Defendants' Pattern of Racketeering Activity***

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1 376. To carry out their illegal and collusive bribery/kickback Scheme Defendants
2 knowingly conducted or participated, directly or indirectly, in the affairs of the Co-payment
3 Circumvention Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C.
4 §§ 1961(1), 1961(5), and 1962(c), and employed the use of the mail and wire facilities, in interstate
5 commerce, to promote, manage, establish, and carry out the Co-Payment Circumvention Enterprise
6 in violation of 18 U.S.C. § 1952 (Travel Act), § 1341 (Mail Fraud), and § 1343 (Wire Fraud).
7 Defendants intended to, and in fact did, commit bribery in violation of state and federal law,
8 specifically 42 U.S.C. § 1320a-7b, Conn. Gen. Stat. §§ 53a-161c and 53a-161d; Fla. Stat. §§ 456.054
9 and 817.505; Mass. Gen. Laws ch. 175H, § 3; Mich. Comp. Laws § 752.1004; Ohio Rev. Code §
10 3999.22; and 5 R.I. Gen. Laws § 548.1-3, and Section 5 of the FTCA (collectively, “unlawful
11 activity”). Defendants used interstate mail and wire facilities with the intent to (1) distribute the
12 proceeds from this unlawful activity and (2) promote, manage, establish, carry on, or facilitate the
13 promotion, management, establishing, or carrying on of this unlawful activity.

14 377. Defendants’ pattern of racketeering likely involved thousands, if not hundreds of
15 thousands, of separate instances of use of the U.S. mail or interstate wire facilities in furtherance of
16 the Co-Payment Circumvention Enterprise. Each of these mailings and interstate wire transmissions
17 constitutes an instance of “racketeering activity” within the meaning of 18 U.S.C. § 1961(1)(B).
18 Collectively, these violations constitute a “pattern of racketeering activity” under 18 U.S.C. §
19 1961(5), to advance Defendants’ intentional and illegal Scheme.

20 378. As set forth throughout this Complaint, Defendants engaged in a scheme to defraud
21 third-party payors, including the Assignors and Class Members. Defendants funneled and steered
22 patients into CVC’s illicit funds for the Jazz Drugs, knowing third-party payors such as the Assignors
23 and Class Members would ultimately bear the cost of the drugs. Defendants knew their Scheme to
24 funnel, steer, and refer patients and funds were violations of federal and state laws including, but not
25 limited to, the AKS and the FCA and that they were transmitting information, fraudulent and
26 otherwise, through mail and wire communications.

379. Defendants' use of the mails and wires to perpetuate their fraudulent Co-Payment Circumvention Enterprise involved thousands of communications which involved, among others, the following:

- a. Communications from Jazz and CVC to patients, steering them to Jazz's co-payment assistance programs utilizing CVC;
- b. Transmittal of bribes and/or kickbacks disguised as "donations" by Jazz to CVC so that CVC could pay the co-payments of Jazz's "customers" in Jazz's co-pay assistance program;
- c. Submission of certifications by Jazz and CVC in which they claimed to be in compliance with federal law, including the AKS and FCA;
- d. Submissions of data from CVC to Jazz so that Jazz could conduct ROI analyses on its "donations" to CVC and to see how much more money it could make by increasing its "donations";
- e. Certifications by CVC that it would determine the eligibility according to a "uniform measure of financial need that is applied in a consistent manner" when in fact CVC emphasized patients taking the Jazz Drugs based on Jazz's bribes and/or kickbacks, not financial need;⁴⁴
- f. Causing false claims, in violation of the FCA and AKS, to be submitted by patients, pharmacies, and providers to Assignors;
- g. Using the mail and wire to mislead the government agencies (i.e., the OIG, IRS, DOJ and equivalent state departments of record) through false certifications and misrepresentations;
- h. Fraudulently conveying ill-gotten gains to Adira and then using the mail and wire to advertise and market Adira's services;

⁴⁴ See CVC's Form 990 Filing, attached as **Exhibit 6**.

- 1 i. Misleading third-party payors, health care providers, investors, government
- 2 agencies, and the general public into believing the legitimacy of Defendant's
- 3 Scheme;
- 4 j. Allowing pharmacies and hubs to access CVC's internal referral software and
- 5 secure messaging center; and
- 6 k. Jazz requesting, and CVC complying, that Jazz's bribes and/or kickbacks
- 7 disguised as "donations" would be used to provide co-payment assistance
- 8 almost exclusively for patients taking the Jazz Drugs.

9 380. Defendants violated the Travel Act by using the mail and wire facilities to commit,
 10 promote, manage, establish, and carry on their bribery and/or kickback Scheme in violation of the
 11 laws of the United States, namely, the AKS, as well as the laws of several States, namely, (1) Conn.
 12 Gen. Stat. §§ 53a-161c and 53a-161d; (2) Fla. Stat. §§ 456.054 and 817.505; (3) Mass. Gen. Laws
 13 ch. 175H, § 3; (4) Mich. Comp. Laws § 752.1004; (5) Ohio Rev. Code § 3999.22; and (6) 5 R.I. Gen.
 14 Laws § 548.1-3; and (7) Section 5 of the FTCA. Defendants further used the mail and wire facilities
 15 to distribute the proceeds of their bribery and/or kickback Scheme.

16 381. Defendants' activity was intended to and did in fact violate the federal AKS by
 17 knowingly and willfully offering (by Jazz) and accepting (by CVC) bribes (i.e., "donations") in return
 18 for CVC referring, accepting referrals for, and arranging for Assignors and Class Members to
 19 purchase, and beneficiaries to receive, Subject Jazz Drugs.

20 382. Defendants' activity was intended to and did in fact violate Conn. Gen. Stat.
 21 §§ 53a-161c and 53a-161d. These two laws prohibit two sides of the same scheme. Under Conn. Gen.
 22 Stat. § 53a-161c(a), it is illegal to "knowingly solicit[], accept[] or agree[] to accept any benefit, in
 23 cash or in kind, from another person upon an agreement or understanding that such benefit will
 24 influence such person's conduct in relation to referring an individual or arranging for the referral of
 25 an individual for the furnishing of any goods, facilities or services to such other person under contract
 26 to provide goods, facilities or services to a local, state or federal agency." This was violated by CVC
 27 accepting money from Jazz to influence CVC's conduct in referring and arranging for the referral of
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beneficiaries of Assignors and Class Members, who are under contract to provide health insurance benefits on behalf of state and federal agencies (e.g., CMS). Similarly, it is illegal under Conn. Gen. Stat. § 53a-161d(a) to “knowingly offer[] or pay[] any benefit, in cash or kind, to any person with intent to influence such person: (1) To refer an individual, or to arrange for the referral of an individual, for the furnishing of any goods, facilities or services for which a claim for benefits or reimbursement has been filed with a local, state or federal agency; or (2) to purchase, lease, order or arrange for or recommend the purchasing, leasing or ordering of any goods, facilities or services for which a claim of benefits or reimbursement has been filed with a local, state or federal agency.” Defendants’ scheme operated in Connecticut and thereby violated these state laws.

383. Defendants’ activity was intended to and did in fact violate Fla. Stat. §§ 456.054 and 817.505. Specifically, under Fla. Stat. § 456.054(2) “[i]t is unlawful for . . . any provider of health care services to offer, pay, solicit, or receive a kickback, directly or indirectly, overtly or covertly, in cash or in kind, for referring or soliciting patients.” Jazz is a provider of health care services and paid kickbacks to CVC, and to pharmacies through CVC, for referring patients to receive the Jazz Drugs. Similarly, under Fla. Stat. § 817.505(1) it is illegal “for any person . . . to (a) [o]ffer or pay a commission, benefit, bonus, rebate, kickback, or bribe, directly or indirectly, in cash or in kind, . . . to induce the referral of a patient or patronage to or from a health care provider or health care facility.” Likewise, subsection (b) prohibits soliciting or receiving the same. Here, Jazz paid, and CVC received bribes to induce the referral of patients to receive the Jazz Drugs. Defendants’ Scheme operated in Florida and resulted in claims being submitted therein and thereby violated these state laws.

384. Defendants’ activity was intended to and did in fact violate Mass. Gen. Laws Ch. 175H, § 3. Specifically, it is illegal for any person to “offer[] or pay[] [(or solicit or receive)] any remuneration, including any bribe or rebate, except as provided in subsection (b), directly or indirectly, overtly or covertly, in cash or in kind to induce any person to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering of any good, facility, service, or item for which payment is or may be made in whole or in part by a health care insurer.

1 385. Defendants' activity was intended to and did in fact violate Mich. Comp. Laws
2 § 752.1004. It is illegal under Michigan law for any person to "solicit[], offer[], pay[], or receive[] a
3 kickback or bribe in connection with the furnishing of goods or services for which payment is or may
4 be made in whole or in part by a health care corporation or health care insurer, or [to] receive[] a
5 rebate of a fee or charge for referring an individual to another person for the furnishing of health care
6 benefits." *Id.* Defendants' Scheme operated in Michigan and resulted in claims being submitted
7 therein and thereby violated this state law.

8 386. Defendants' activity was intended to and did in fact violate Ohio Rev. Code § 3999.22.
9 Under Ohio law, "No person shall knowingly solicit, offer, pay, or receive any kickback, bribe, or
10 rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual
11 for the furnishing of health care services or goods for which whole or partial reimbursement is or may
12 be made by a health care insurer[.]" Jazz offered and paid, and CVC solicited and received, bribes in
13 return for CVC referring patients to receive the Jazz Drugs for which the non-co-payment portion
14 was paid by a health insurer (i.e., Assignors and Class Members). Defendants' scheme operated in
15 Ohio and resulted in claims being submitted therein and thereby violated this state law.

16 387. Defendants' activity was intended to and did in fact violate 5 R.I. Gen. Laws § 5-48.1-
17 3. Under Rhode Island law, it is illegal for any person to "knowingly and willfully solicit[] or receive[]
18 [(or offer or pay)] any remuneration (including any kickback, bribe, or rebate) directly or indirectly,
19 overtly or covertly, in cash or in kind; (1) in return for referring an individual to a person for the
20 furnishing, or arranging for the furnishing, of any health care service or item; or (2) in return for
21 purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering, any
22 health care good, facility, service, or item." Jazz offered and paid, and CVC solicited and received,
23 bribes in return for CVC referring patients to receive the Jazz Drugs and arranging for the purchase
24 of same by funneling Jazz's money to these patients. Defendants' Scheme operated in Rhode Island
25 and resulted in claims being submitted therein and thereby violated this state law.

26 388. The predicate acts violating the Travel Act, as well as mail and wire fraud, had the
27 same purpose: to make money by growing CVC's funds as large as possible so that CVC's officers
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1 and directors could pay themselves millions, and so that Jazz could get as many “customers” as
2 possible for the Jazz Drugs at the expense of the Assignors and Class Members.

3 389. All of the predicate acts detailed above, including the certifications made by Jazz and
4 CVC, as well as the wire communications in furtherance of their Scheme, were done willingly, and
5 in furtherance of the purpose of the Scheme.

6 390. If the certifications and misrepresentations by Jazz to CMS had not been made,
7 Assignors would not have purchased Jazz’s products. If CVC’s certifications had not been made,
8 CVC would not have been permitted to administer its Narcolepsy and Severe Chronic Disease Funds
9 and the Assignors and Class Members would not have paid for the claims resulting from the unlawful
10 conduct. If the Scheme did not exist, pharmacies would have received substantially less co-pay
11 revenues, and the pharmacies would not have submitted AKS-tainted claims to Assignors and Class
12 Members. If the Scheme did not exist, Jazz would not have been able to continuously increase the
13 prices of Jazz Drugs and remain profitable to the extent that it was.

14 391. These predicate acts allowed the continuance of the Scheme to increase the quantity
15 of the Jazz Drugs and maintain supra-competitive prices. As a result of the Scheme, Assignors and
16 Class Members paid supra-competitive prices for Subject Jazz Drugs at artificially inflated volumes.

17 392. Defendants, including their officers, directors, agents, and principals of both
18 organizations, participated in all of the predicate acts. These individuals sent or caused to be sent false
19 certifications and misrepresentations through the mail and wire facilities. These individuals
20 repeatedly, and continuously, used the mail and wires in furtherance of the Scheme.

21 393. The direct and intended victims of the Scheme were the Assignors and Class Members.

22 394. The violations of the Travel Act and Mail and Wire Fraud included transmission of
23 false claims and the unlawful transmission of data and communications to further the racketeering
24 Scheme over a period of *at least* four years involving harm to multiple parties.

25 395. CVC was involved in similar fraudulent schemes with other drug manufacturers. It
26 was engaged in similar schemes with Actelion, United Therapeutics, and Lundbeck, each of which
27 resulted in settlements with the United States for violations of the AKS and FCA in 2018. Specifically,
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1 Actelion settled for \$360 million, United Therapeutics settled for \$230 million, and Lundbeck settled
2 for \$52.6 million. CVC's multi-faceted fraud involved multiple victims and predicate acts and is the
3 type of broad and persistent racketeering activity that RICO was intended to stop.

4 396. As CVC's successor, Adira is liable for CVC's conduct and is also independently
5 liable for the conduct Adira engaged in that was in furtherance of the concealment and execution of
6 the Scheme.

7 397. The Co-payment Circumvention Enterprise and the predicate acts proximately caused
8 injury to Assignors' and Class Members' business and property by, among other ways, triggering the
9 Assignors' and Class Members' duty to purchase the Jazz Drugs and by driving up the cost of the
10 Jazz Drugs. Defendants' Scheme rendered the claims for the Jazz Drugs unpayable and Assignors
11 and Class Members would not have (and could not have) paid if Defendants had not concealed their
12 Scheme.

13 398. Accordingly, Defendants' violations of 18 U.S.C. §1962(c) directly and proximately
14 caused injuries and damages to Assignors and Class Members, entitling Plaintiffs to bring this action
15 for three times their actual damages, as well as injunctive/equitable relief, costs, and reasonable
16 attorneys' fees pursuant to 18 U.S.C. § 1964(c).

17 **SECOND CLAIM FOR RELIEF**

18 **Violation of 18 U.S.C. § 1962(d) Through the Co-Payment Circumvention Enterprise**

19 *Against All Defendants*

20 399. Plaintiffs re-allege and incorporate by reference paragraphs 1-356 of this Complaint
21 as though set forth at length herein.

22 400. Section 1962(d) makes it unlawful for "any person to conspire to violate" section
23 1962(c), among other provisions.

24 401. Defendants violated § 1962(d) by conspiring to violate § 1962(c). The object of this
25 conspiracy was to conduct or participate in, directly or indirectly, the conduct of the affairs of the Co-
26 Payment Circumvention Enterprise described previously, through a pattern of racketeering activity.

1 402. Defendants knowingly agreed that Jazz would perform services that would facilitate
2 the illicit activities of the Co-payment Scheme. Jazz steered the Jaz Drugs patients away from its
3 manufacturer-sponsored free-drug fund and into CVC's Narcolepsy and Severe Chronic Disease
4 Funds. Jazz also provided CVC with "donations" so that CVC could pay the co-payments of Jazz's
5 "customers" in CVC's funds. Jazz also sent certifications over the interstate mails and wires claiming
6 it was in compliance with federal law, including the AKS and FCA. Jazz also used the data CVC sent
7 it, in violation of the AKS and FCA, to determine how much money it was making from its
8 "donations" to CVC and how much more money it could make by increasing its "donations."

9 403. Indeed, Jazz and CVC were not engaged in parallel conduct but were working together
10 and had a meeting of the minds that they could both profit from the Co-payment Circumvention
11 Enterprise. The shared data showed how much money Jazz made the prior year before from its
12 "donations" to CVC and how much more it could make by increasing its "donations." It thus set out
13 a roadmap of illegal activities and profits.

14 404. Further, Defendants knowingly agreed that CVC would perform services that would
15 facilitate the activities of the Co-Payment Circumvention Enterprise and those who were running it
16 in an illegal manner. Some of the services that CVC performed were steering people into its funds
17 and helping to enroll patients into Medicare and Medicaid Programs. Jazz would then pay CVC
18 agreed-upon bribes and/or kickbacks for each patient CVC successfully enrolled in Medicare and
19 Medicaid Programs for the Jazz Drugs.

20 405. CVC also sent certifications over the interstate mails and wires claiming it was in
21 compliance with federal law, including the AKS and FCA. CVC also sent data to Jazz, in violation
22 of the AKS and FCA, so Jazz could see how much money it was making from its "donations" to CVC
23 and how much more money it could make by increasing its "donations." Indeed, this sharing of data
24 shows that Jazz and CVC were not engaged in parallel conduct but were working together and had a
25 meeting of the minds that they could both profit from the Co-payment Scheme. CVC knew that the
26 more money it accepted in "donations" from Jazz, the more money would go into the pockets of
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1 CVC's officers and directors. By illegally giving Jazz this data, CVC was soliciting greater
2 contributions.

3 406. Further, Jazz and CVC knowingly agreed to perform services that would facilitate the
4 activities of the Co-Payment Circumvention Enterprise and those who were running it in an illegal
5 manner. Jazz steered people towards CVC's co-payment assistance funds by using CVC data to
6 ensure Jazz could verify that its "donations" provided co-pays for the Jazz Drugs. Jazz and CVC
7 caused false certifications to be sent over the interstate mail and wire facilities claiming they were in
8 compliance with federal law, including the AKS and FCA. CVC sent Jazz data, in violation of the
9 AKS and FCA, so that Jazz could see how much money it was making from its "donations" to CVC,
10 and how much more money it could make by increasing its "donations." Indeed, this conduct shows
11 that Defendants did not engage in parallel conduct but worked together and had a meeting of the
12 minds that they could each profit from the Co-payment Scheme. Jazz knew that if it provided more
13 "donations," CVC would provide more co-pay assistance, thereby increasing Jazz's profits. Thus, by
14 illegally providing data to Jazz, CVC managed to increase its own profits—as well as Jazz's profits.

15 407. Defendants knowingly agreed that one or all of them would commit at least two
16 instances of Travel Act violations or mail and wire fraud (or cause an innocent third-party to send
17 false statements over the mails and wires). Defendants had actual or constructive knowledge that
18 CVC had certified to HHS that it would not share data with manufacturers, allow manufactures to
19 exert influence over it, steer people to particular drugs, or serve as a conduit for drug manufacturers.
20 In short, Defendants knew that CVC had certified that it would abide by the AKS and FCA.
21 Defendants knew that the Scheme they were engaged in or were going to engage in was going to
22 make all these certifications false. They also knew that each time a pharmacy filled a prescription for
23 someone in CVC's funds, any certifications the pharmacist made that he or she would abide by federal
24 law would be false. Jazz also knew that any certifications it made to HHS or the Government about
25 its compliance with federal law would be false.

26 408. Defendants knew that any communications they had over the telephone, email, or text
27 message in furtherance of the Scheme would be predicate acts.

409. Defendants agreed to pursue the same objective of profiting illegally from the Co-payment Scheme. They agreed to divide the work of accomplishing this objective. Jazz would make the “donations;” CVC would provide data; and they would both steer clients and make false certifications. Defendants intended to further this endeavor, which, as described above, when completed, amounted to a violation of 18 U.S.C. § 1962(c) that proximately and directly caused injury to the Assignors and Class Members.

410. As CVC’s successor, Adira is liable for CVC’s conduct and is also independently liable for the conduct Adira engaged in that was in furtherance of the concealment and execution of the Scheme.

411. Plaintiffs bring this action for three times their actual damages, as well as injunctive/equitable relief, costs, and reasonable attorneys’ fees pursuant to 18 U.S.C. § 1964(d).

THIRD CLAIM FOR RELIEF

Violations of State Consumer Protection Laws

Against All Defendants

412. Plaintiffs re-allege and incorporate by reference paragraphs 1-356 of this Complaint as though set forth at length herein.

413. Defendants engaged in unfair competition or unfair, unconscionable, deceptive, acts or practices in violation of the state consumer protection laws, as set forth below.

414. Defendants directly misrepresented to Assignors and the Class Members that they were complying with federal and state laws, including laws against bribery, kickbacks, and false claims to the government.

415. Defendants utilized the Scheme to eliminate price sensitivity in order to raise prices for the Jazz Drugs to supra-competitive levels.

416. Defendants intended for payers such as Assignors and Class Members to rely on these certifications. The intention may be inferred by the very nature of the representation, whose sole purpose was to procure payment for the Jazz Drugs. These representations and certifications were made in an effort by Defendants to have the consuming public use the CVC fund and were addressed

1 to the market generally by having improper and unnecessary prescriptions for the Jazz Drugs paid for
2 by Medicare, Assignors, and the Class Members. The ultimate consequence of this conduct is a
3 significant injury to the consuming public by, among other things, imposing additional costs on the
4 taxpaying public for Medicare.

5 417. Assignors and the Class Members relied on these misrepresentations to their detriment,
6 which were material to their decision to pay for the Jazz Drugs.

7 418. As CVC's successor, Adira is liable for CVC's conduct and is also independently
8 liable for the conduct Adira engaged in that was in furtherance of the concealment and execution of
9 the Scheme.

10 419. Assignors and the Class Members were directly and proximately injured by
11 Defendants' conduct suffered an injury in fact, and suffered actual, ascertainable damages.

12 420. Assignors and the Class Members would not have reimbursed for nearly as much of
13 the Jazz Drugs as they did, had Defendants refrained from engineering the false representations or
14 otherwise disclosed its Scheme. Likewise, Assignors and the Class Members would not have paid
15 nearly as much for each prescription of the Jazz Drugs as they did, had Defendants not eliminated
16 price sensitivity through the Co-payment Scheme.

17 421. There was and is a gross disparity between the price that Plaintiffs' Assignors paid and
18 continue to pay for their direct and indirect purchases of the Subject Jazz Drugs and the value
19 received, and prices for the Subject Jazz Drugs should be much lower, but for Jazz's unlawful scheme.

20 422. Accordingly, Plaintiffs and the Class Members in each of the below jurisdictions, seek
21 damages (including statutory damages where applicable), to be trebled or otherwise increased as
22 permitted by a jurisdiction's consumer protection law, and cost of suit, including reasonable
23 attorneys' fees, to the extent permitted by the below state laws.

24 423. By engaging in the foregoing conduct, Jazz has engaged in unfair competition and/or
25 deceptive acts and practices in violation of the following state consumer protection laws:

(1) Connecticut Unfair Trade Practices Act (Conn. Gen. Stat. §§ 42-110a et seq.)

424. Defendants' conduct occurred in "trade" or "commerce" within the meaning of Conn. Gen. Stat. § 42-110a(4) ("Connecticut UTPA").

425. The Connecticut UTPA provides that "no person shall engage in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Conn. Gen. Stat. § 42-110b(a).

426. Defendants' conduct constitutes "unfair or deceptive" acts in violation of the Connecticut UTPA.

427. Defendants' illegal conduct substantially affected Connecticut commerce and consumers.

428. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased payments for the Jazz Drugs herein.

429. Defendants' conduct alleged in this Complaint occurred throughout the United States, including in the State of Connecticut.

430. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the Jazz Drugs in the State of Connecticut.

431. Simultaneously with the filing of this Complaint, Plaintiffs served a copy on the Attorney General and Commissioner of Consumer Protection pursuant to Conn. Gen. Stat. § 42-110g.

432. Plaintiffs are entitled to recover their actual damages, punitive damages, and attorneys' fees pursuant to Conn. Gen. Stat. § 42-110g.

(2) Florida Deceptive & Unfair Trade Practices Act (Fla. Stat. §§ 501.201 et seq.)

433. Plaintiffs, Assignors, and the Class Members are "interested persons" and "consumers" within the meaning of the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"). Fla. Stat. § 501.203(6)-(7).

434. Defendants are engaged in "trade or commerce" within the meaning of Fla. Stat. § 501.203(8).

1 435. FDUTPA prohibits “[u]nfair methods of competition, unconscionable acts or
2 practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce[.]” Fla.
3 Sta. § 501.204(1).

4 436. Defendants’ conduct constitutes “unconscionable acts or practices, and unfair or
5 deceptive acts or practices” under FDUTPA.

6 437. Defendants knew or should have known that their conduct was in violation of
7 FDUTPA.

8 438. Defendants’ illegal conduct substantially affected Florida commerce and consumers.

9 439. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual
10 damages as a direct and proximate result of Defendants’ unfair and deceptive practices and omissions
11 and/or misrepresentations, at a minimum, in the form of increased number and size of payments for
12 the Jazz Drugs described herein.

13 440. Defendants’ conduct alleged in this Complaint occurred throughout the United States,
14 including in the State of Florida.

15 441. Plaintiffs’ analysis of its Assignors’ data identified one or more purchases of the Jazz
16 Drugs in the State of Florida.

17 442. Plaintiffs seek to recover against each Defendant the amount of their actual damages,
18 attorneys’ fees, and costs pursuant to Fla. Stat. §§ 501.211(2) and 501.2105(1).

19 **(3) Massachusetts Regulation of Business Practice & Consumer Protection Act (Mass.**
20 **Gen. Laws Ch. 93A, §§ 1 et seq.)**

21 443. Assignors, the Class Members, and Defendants are “persons” within the meaning of
22 the Massachusetts Regulation of Business Practice & Consumer Protection Act (“Massachusetts
23 CPA”). Mass. Gen. Laws Ch. 93A, § 1(a).

24 444. Defendants are engaged in “trade or commerce” within the meaning of Mass. Gen.
25 Laws Ch. 93A, § 1(b).

26 445. Defendants’ conduct, and Plaintiffs’ injury occurred primarily and substantially within
27 the Commonwealth of Massachusetts.

1 446. The Massachusetts CPA makes unfair methods of competition and unfair or deceptive
2 acts or practices in the conduct of any trade or commerce unlawful. Mass. Gen. Laws Ch. 93A, § 2(a).

3 447. Defendants' conduct constitutes "unfair or deceptive acts or practices" under
4 Massachusetts CPA.

5 448. Defendants knew or should have known that their conduct was in violation of
6 Massachusetts CPA.

7 449. Defendants' illegal conduct substantially affected Massachusetts commerce and
8 consumers.

9 450. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual
10 damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions
11 and/or misrepresentations, at a minimum, in the form of increased payments for the Jazz Drugs
12 described herein.

13 451. Defendants' conduct alleged in this Complaint occurred throughout the United States,
14 including in the State of Massachusetts.

15 452. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the Jazz
16 Drugs in the State of Massachusetts.

17 453. Plaintiffs seek monetary relief against Defendants measured as the greater of (a) actual
18 damages in an amount to be determined at trial and (b) statutory damages in the amount of \$25 for
19 each Plaintiff. Because Defendants' conduct was committed willfully and knowingly, Plaintiffs are
20 entitled to recover up to three times actual damages, but no less than two times actual damages
21 pursuant to Mass. Gen. Laws Ch. 93A, §§ 9 and 11.

22 454. Plaintiffs also seek punitive damages, and attorneys' fees, costs, and any other just and
23 proper relief available under the Massachusetts CPA.

24 **(4) Michigan Consumer Protect Act (Mich. Comp. Laws §§ 445.901 et seq.)**

25 455. Defendants' conduct occurred in "trade" or "commerce" within the meaning of
26 Michigan Consumer Protection Act ("Michigan CPA"). Mich. Comp. Laws § 445.902(g).

1 456. Defendants are “persons” within the meaning of Michigan CPA. Mich. Comp. Laws
2 § 445.902(d).

3 457. The Michigan CPA provides that “Unfair, unconscionable, or deceptive methods, acts,
4 or practices in conduct of trade or commerce are unlawful.” Mich. Comp. Laws § 445.903(1).

5 458. Defendants’ conduct constitutes “unfair, unconscionable, or deceptive” methods, acts,
6 or practices under the Michigan CPA.

7 459. Defendants’ conduct includes, but is not limited to, several categories defined in the
8 Michigan Consumer Protection Act. *See* Mich. Comp. Laws § 445.903(1)(a), (c), (s), (u), (w), and
9 (z).

10 460. Defendants’ conduct substantially affected Michigan trade or commerce, and
11 consumers.

12 461. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual
13 damages as a direct and proximate result of Defendants’ unfair, unconscionable, or deceptive
14 practices and omissions and/or misrepresentations, at a minimum, in the form of increased payments
15 for the Jazz Drugs herein.

16 462. Defendants’ conduct alleged in this Complaint occurred throughout the United States,
17 including the State of Michigan.

18 463. Plaintiffs’ analysis of its Assignors’ data identified one or more purchases of the Jazz
19 Drugs in the State of Michigan.

20 464. Plaintiffs are entitled to recover their actual damages and reasonable attorney fees
21 pursuant to Mich. Comp. Laws § 445.911(2)-(3).

22 **(5) New York General Business Law (N.Y. Gen. Bus. Law §§ 349 et seq.)**

23 465. The New York General Business Laws (“New York GBL”) makes unlawful
24 “[d]eceptive acts or practices in the conduct of any business, trade or commerce.” N.Y. Gen. Bus.
25 Law § 349.

26 466. Defendants’ conduct constitutes “deceptive acts” in violation of the New York GBL.
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1 467. Defendants' conduct eliminated price sensitivity and raised prices in the relevant
2 markets for the Jazz Drugs, which necessarily impacted consumers at large.

3 468. Defendants' conduct was consumer oriented since it was necessarily directed at
4 Plaintiffs, consumers and/or other similarly situated entities.

5 469. Defendants' illegal conduct substantially affected New York commerce and
6 consumers.

7 470. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual
8 damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions
9 and/or misrepresentations, at a minimum, in the form of increased payments for the Jazz Drugs
10 described herein.

11 471. Defendants' conduct alleged in this Complaint occurred throughout the United States,
12 including in the State of New York.

13 472. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the Jazz
14 Drugs in the State of New York.

15 473. 424. As a result of the foregoing willful, knowing, and wrongful conduct of
16 Defendants, Plaintiffs have been damaged in an amount to be proven at trial, and seek all just and
17 proper remedies, including but not limited to actual damages or \$50, whichever is greater, treble
18 damages up to \$1,000, punitive damages to the extent available under the law, reasonable attorneys'
19 fees and costs, an order enjoining Defendants' deceptive and unfair conduct, and all other just and
20 appropriate relief available pursuant to N.Y. Gen. Bus. Law § 349.

21 **(6) Ohio Consumer Protection Laws (Ohio Rev. Code Ann. §§ 1345 et seq., 4164 et seq.)**

22 474. Defendants, Assignors, and the Class Members are "persons" within the meaning of
23 the Ohio Consumer Sales Practice Act, Ohio Rev. Code Ann. §§ 1345.01 et seq. ("Ohio CSPA") and
24 the Ohio Deceptive Trade Practices Act, Ohio Rev. Code Ann. §§ 4165.01 et seq. ("Ohio DTPA").

25 475. Defendants are "suppliers" within the meaning of the Ohio CSPA. Ohio Rev. Code
26 Ann. § 1345.01

1 476. Defendants engaged in trade or commerce within the meaning of the Ohio CSPA and
2 Ohio DTPA.

3 477. The Ohio CSPA specifies “No supplier shall commit an unfair or deceptive act or
4 practice.” Ohio Rev. Code Ann. § 1345.02.

5 478. The Ohio DTPA declares it unlawful for any person to engage in a deceptive practice
6 in the course of the person’s business, vocation, or occupation. Ohio Rev. Code Ann. § 4165.02.

7 479. Defendants’ conduct constituted “unfair, deceptive acts or practices” in violation of
8 the Ohio CSPA and Ohio DTPA.

9 480. Defendants knew or should have known that their conduct was in violation of both the
10 Ohio CSPA and Ohio DTPA.

11 481. Defendants’ illegal conduct substantially affected Ohio commerce and consumers.

12 482. Assignors and the Class Members relied upon Defendants’ material
13 misrepresentations regarding the certifications, their compliance with federal and state laws,
14 including laws against bribery, kickbacks, and false claims to the government.

15 483. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual
16 damages as a direct and proximate result of Defendants’ unfair and deceptive practices and omissions
17 and/or misrepresentations, at a minimum, in the form of increased payments for the Jazz Drugs
18 described herein.

19 484. 435. Defendants’ conduct alleged in this Complaint occurred throughout the United
20 States, including in the State of Ohio.

21 485. 436. Plaintiffs’ analysis of its Assignors’ data identified one or more purchases of
22 the Jazz Drugs in the State of Ohio.

23 486. 437. Plaintiffs seek actual economic losses, punitive damages, attorney’s fees, and
24 any other just and proper relief available pursuant to the Ohio CSPA and Ohio DTPA.

25 **(7) Wisconsin Deceptive Trade Practices Act (Wis. Stat. §§ 100.18 et seq.)**

26 487. Assignors and the Class Members are part of “the public” under the Wisconsin
27 Deceptive Trade Practices Act (“Wisconsin DTPA”). Wis. Stat. § 100.18(1).

1 488. Assignors and the Class Members are “persons” under Wis. Stat. § 100.18(1).

2 489. Each Defendant is a “person, firm, corporation or association” under Wis. Stat. §
3 100.18(1).

4 490. The Wisconsin DTPA makes unlawful any “representation or statement of fact, which
5 is untrue, deceptive or misleading.” Wis. Stat. § 100.18(1).

6 491. Defendants’ conduct constitutes “representation[s] or statement[s] of fact which
7 [were] untrue, deceptive or misleading” in violation of the Wisconsin DTPA.

8 492. Defendants knew or should have known that their conduct violated the Wisconsin
9 DTPA.

10 493. Defendants’ illegal conduct substantially affected Wisconsin commerce and
11 consumers.

12 494. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual
13 damages as a direct and proximate result of Defendants’ unfair and deceptive practices and omissions
14 and misrepresentations, at a minimum, in the form of increased payments for the Subject Jazz Drugs.

15 495. Defendants’ conduct alleged in this Complaint occurred throughout the United States,
16 including in the State of Wisconsin.

17 496. Plaintiffs’ analysis of its Assignors’ data identified one or more purchases of the
18 Subject Jazz Drugs in the State of Wisconsin.

19 497. No business relationship, contractual or otherwise, existed or exists between
20 Assignors, the Class Members, and Defendants.

21 498. Plaintiffs seek damages, court costs, and attorneys’ fees under Wis. Stat.
22 §100.18(11)(b)(2), and any other just and proper relief available under the Wisconsin DTPA.

23 **FOURTH CLAIM FOR RELIEF**

24 **Unjust Enrichment Under State Law**

25 *Against All Defendants*

26 499. Plaintiffs re-allege and incorporate by reference paragraphs 1-356 of this Complaint
27 as though set forth at length above.

1 500. Defendants have benefitted from artificially inflated profits on the sale of the Jazz
2 Drugs resulting from the unlawful and inequitable acts alleged in this Complaint.

3 501. Defendants' financial benefit resulting from its unlawful and inequitable acts is
4 traceable to overpayments for direct or indirect purchases of the Jazz Drugs by the Assignors and
5 Class Members.

6 502. The Assignors and Class Members afforded Defendants an economic benefit in the
7 form of profits, and other forms of compensation from unlawful overcharges and monopoly profits
8 to the economic detriment of the Assignors and Class Members.

9 503. Plaintiffs' analysis of its Assignors' data identified one or more purchases of Subject
10 Jazz Drugs in each of these States and Territories:

- 11 a. Arizona;
- 12 b. Connecticut;
- 13 c. Florida;
- 14 d. Massachusetts;
- 15 e. Nevada;
- 16 f. New York;
- 17 g. Ohio;
- 18 h. Puerto Rico; and
- 19 i. Wisconsin.

20 504. Defendants' conduct directly resulted in the unjust enrichment of the Defendants
21 through the sale of the Jazz Drugs in each of the States and Territory mentioned above.

22 505. It would be futile for the Assignors and Class Members to seek a remedy from any
23 party with whom they have privity of contract with for its direct or indirect purchases of the Jazz
24 Drugs.

25 506. It would be futile for the Assignors and Class Members to seek to exhaust any remedy
26 against the immediate intermediary in the chain of distribution from which the Assignors and Class
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Members purchased the Jazz Drugs, as they are not liable and would not compensate the Assignors and Class Members for unlawful conduct caused by Defendants.

507. The economic benefit of overcharges and artificially inflated volumes of prescriptions derived by Defendants through charging supra-competitive and artificially inflated prices for the Jazz Drugs is a direct and proximate result of Defendants' unlawful conduct.

508. The economic benefits derived by Defendants rightfully belong to the Assignors and Class Members, as they paid anticompetitive and monopolistic prices beginning in at least January 1, 2011, through present, and they will continue to do effects of Defendants' illegal conduct cease.

509. It would be inequitable under unjust enrichment principles under the aforementioned states and territories for Defendants to be permitted to retain any of the overcharges for the Jazz Drugs derived from Defendants' unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

510. As CVC's successor, Adira is liable for CVC's conduct and is also independently liable for the conduct Adira engaged in that was in furtherance of the concealment and execution of the Scheme.

511. Defendants are aware of and appreciates the benefits bestowed upon it by the Assignors and the Class Members.

512. Defendants should be compelled to disgorge all unlawful or inequitable proceeds received in a common fund for Plaintiffs' benefit.

513. A constructive trust should be imposed on all unlawful or inequitable sums received by Defendants traceable to the Assignors and Class Members.

FIFTH CLAIM FOR RELIEF

Violations of the Civil Remedies for Criminal Practices Act, Fla. Stat. 77101, et seq.

Against All Defendants

514. Plaintiffs re-allege and incorporate by references paragraphs 1-356 of this Complaint as if fully set forth herein.

1 515. At all times, as set forth above, Defendants' actions were unlawful under Fla. Stat. §
2 772.103(3), as they were all "employed by, or associated with, any enterprise through a pattern of
3 criminal activity."

4 516. Defendants violated Fla. Stat. §§ 772.101 *et seq.*, by participating in or conducting the
5 affairs of the Co-Payment Circumvention Enterprise (as described more fully above) through a pattern
6 of racketeering activity.

7 517. Plaintiffs, Assignors, and the Class Members are "persons" as defined in Fla. Stat. §
8 1.01, injured in their business or property, through Defendants' racketeering violations.

9 ***Description of the Co-Payment Circumvention Enterprise***

10 518. Defendants are "persons" within the meaning of Section 1.01, Florida Statutes.

11 519. Jazz and CVC are members of and constitute an "association in-fact enterprise."

12 520. The Co-Payment Circumvention Enterprise is an association-in-fact of individuals and
13 corporate entities within the meaning of Section § 772.101, Florida Statutes, and consists of "persons"
14 associated together for a common purpose.

15 521. The purpose of the Co-Payment Circumvention Enterprise was to maximize Jazz's
16 profits and CVC's executive compensation.

17 522. The Co-Payment Circumvention Enterprise had an ongoing organization with an
18 ascertainable structure and functioned as a continuing unit with separate roles and responsibilities.
19 Jazz is the source of the schemes alleged herein, including providing kickbacks to subsidize payments
20 for the Subject Jazz Drugs whose co-payments were provided by CVC.

21 523. For CVC's part, CVC accepted Jazz's kickbacks and provided unlawful payments for
22 the Subject Jazz Drugs involving beneficiaries in Florida.

23 524. Jazz and CVC, individually and collectively, fulfilled their roles in the Co-Payment
24 Circumvention Enterprise.

25 525. Jazz and CVC were distinct legal entities with distinct purposes. Jazz is the architect
26 of the Co-Payment Circumvention Enterprise, with the sole purpose to make as much money off of
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1 the Subject Jazz Drugs as possible before generic competition entered the market. For CVC, it was to
2 raise the amount of money in the funds to justify paying higher salaries to their executives.

3 526. The Co-Payment Circumvention Enterprise had an existence that was distinct from the
4 pattern of racketeering in which Jazz and CVC engaged. Jazz and CVC conspired with each other to
5 minimize and/or conceal the amount of information Assignors received about the claims for payment
6 of the Jaz Drugs involving beneficiaries in Florida, materially resulting in Assignors (including those
7 headquartered, those who have their principal place of business, and those who operate in Florida)
8 reimbursing the purchase price of the Jazz Drugs that they would not have otherwise paid for. *See*
9 Fla. Stat. § 817.234 (“A person commits insurance fraud punishable as provided in subsection (11) if
10 that person, with the intent to injure, defraud, or deceive any insurer: 1. Presents or causes to be
11 presented any written or oral statement, as part of, or in support of, a claim for payment or other
12 benefit pursuant to an insurance policy or a health maintenance organization subscriber or provider
13 contract, knowing that such statement contains any false, incomplete, or misleading information
14 concerning any fact or thing material to such claims[.]”).

15 527. At all relevant times, Defendants operated, controlled, and managed the Co-Payment
16 Circumvention Enterprise, through a variety of actions. First, CVC falsely represented the level of
17 control that Jazz had over CVC in the PAP to the OIG on numerous occasions. Second, Defendants
18 failed to disclose a material fact about the existence of the kickbacks and/or bribes in violation of Fla.
19 Stat. § 817.234, (i.e., causing pharmacies to submit false submissions of payments to the Assignors
20 and the Class Members.).

21 528. Defendants’ participation in the Co-Payment Circumvention Enterprise was necessary
22 for the successful operation of the schemes. The members of the Co-Payment Circumvention
23 Enterprise all served a common purpose, which was to increase the fund to an enormous size while
24 knowing each payment was a bribe and/or kickback, while minimizing the amount of information the
25 Assignors, Class Members, and allegedly innocent third-party pharmacies (including those
26 headquartered, those who have their principal place of business, and operate in Florida), knew about
27 the program. These affirmative acts and strategic omissions were material to the Assignors’ and Class
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1 Members' decision to issue payment for the Jazz Drugs, including for claims involving beneficiaries
2 in Florida. The Co-Payment Circumvention Enterprise's actions maximized the revenue and
3 profitability of the Enterprises' members by knowingly causing payments for the Jazz Drugs,
4 including for claims involving beneficiaries in Florida.

5 529. Fla. Stat. § 772.102 provides that criminal activity is any activity chargeable by
6 indictment or information by among other statutes Fla. Stat. § 817.234. Section 817.234 criminalizes
7 situations where health care companies, such as the Assignors and Class Members, are provided
8 incomplete or misleading information about any fact or thing material to a claim for payment. Jazz
9 and CVC violated Fla. Stat. § 817.234 by providing incomplete or misleading information material
10 to the Assignors' and Class Members' decision to issue payment for the Jazz Drugs, including for
11 claims involving beneficiaries in Florida.

12 530. Defendants committed numerous acts of racketeering by providing incomplete or
13 misleading information related to the Jazz Drugs, including for claims involving beneficiaries in
14 Florida. Jazz and CVC knew or had reason to know that they were providing incomplete or misleading
15 information about these claims.

16 531. Defendants knew or had reason to know that they were not providing complete or non-
17 misleading information under Fla. Stat. § 817.234. Despite knowledge of these facts, they induced
18 the Assignors and Class Members to make payment for claims, including for claims involving
19 beneficiaries in Florida, that they otherwise would not have paid. Instead, Defendants knowingly
20 provided incomplete information to enrich their bottom line.

21 532. Based on these omissions, the Assignors and Class Members provided payments for
22 the Jazz Drugs throughout the United States, including Florida, based on half-truths, inaccurate
23 information, and deliberate omissions. Defendants' omissions were material to the payment of the
24 Jazz Drugs that the Assignors and Class Members provided payment for. Had the Assignors and Class
25 Members known of the Co-Payment Scheme, they would not have submitted payment for the Jazz
26 Drugs.

533. The Assignors and Class Members were the primary and intended victims of Defendants' unlawful scheme. The Assignors paid for the Jazz Drugs throughout the United States, including Florida, based on Defendants' omissions of material information under pursuant under to Fla. Stat. § 817.234.

534. As part of this Scheme, Defendants caused pharmacies to submit false certifications and misled the Assignors and Class Members into reimbursing prescriptions of the Jazz Drugs. Jazz, CVC, and Adira conducted or participated, directly or indirectly, in the Co-Payment Circumvention Scheme through a pattern of unlawful activity.

535. As CVC's successor, Adira is liable for CVC's conduct and is also independently liable for the conduct Adira engaged in that was in furtherance of the concealment and execution of the Scheme.

536. By reason of and as a result of Defendants' conduct, the Assignors and Class Members were injured in their business or property.

537. Defendants' violations have directly and proximately caused injuries and damages to Assignors, Plaintiffs, and the Class Members. The Assignors, Plaintiffs, and Class Members have a right to bring this action for these damages.

538. Under Fla. Stat. § 772.11, Plaintiffs and the Class Members seek their reasonable attorneys' fees and costs associated with prosecution of this action.

SIXTH CLAIM FOR RELIEF

Violation of Va. Code Ann. §§ 55.1-400 *et seq.* (formerly §§ 55-80 *et seq.*)

Against CVC and Adira

539. Plaintiffs re-allege and incorporate by references paragraphs 1-356 of this Complaint as if fully set forth herein.

540. As detailed above, during CVC's dissolution process, all (or nearly all) of CVC's unrestricted and unobligated assets were given, assigned, and/or transferred to Adira—including some transfers when Adira was still known as FPH—including millions of dollars in cash, an

1 unknown amount of investment assets, and a long list of office equipment and other valuable personal
2 property.

3 541. During the Co-Payment Scheme, Plaintiffs became bona fide creditors under Va. Code
4 Ann. §§ 55.1-400 *et seq.* as victims of the Co-Payment Scheme.

5 542. All or nearly all of CVC's gifts, transfers, conveyances, and assignments to Adira and
6 FPH are voided as a matter of law as voluntary and/or fraudulent conveyances pursuant to Va. Code
7 Ann. § 55.1-400. The millions of dollars, investment assets, and set of personal property that CVC
8 transferred to Adira and FPH was not upon consideration deemed valuable in law.

9 543. When CVC completed these transfers, CVC was in the process of completing its
10 disillusionment. As CVC's transferred all of its remaining unrestricted and unobligated assets to
11 Adira, this transfer had the effect of rendering CVC insolvent.

12 544. At the time that CVC transferred its assets to Adira, Adira intended to continue CVC's
13 business by using its assets for its gain and to the detriment of Plaintiffs and the Class Members.

14 545. The aforementioned transfers were made with an actual intent to hinder, delay and
15 defraud Plaintiffs.

16 546. The aforementioned transfers were made in reckless disregard for the Plaintiffs' rights
17 and were made to leave CVC insolvent without the ability to pay its liabilities as they came due.

18 547. If any consideration was received by Adira in exchange for the asset transfers, such
19 consideration was a sham, nominal consideration, inadequate and far less than a reasonably equivalent
20 value for such assets.

21 548. At the time the transfers were made, Adira knew or should have known that the
22 consideration for the transfers was nonexistent, a sham, nominal consideration, inadequate, and/or far
23 less than a reasonably equivalent value for such assets.

24 549. Adira's transfers were not made in good faith. Because Adira had the knowledge
25 aforesaid, it is not a bona fide purchaser.

26 550. The transfers discussed are fraudulent transfers under Va. Code Ann. § 55.1-400.
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557. As a successor, Adira is jointly and severally liable to Plaintiffs and the Class Members for CVC's involvement in the Co-Payment Scheme.

EIGHTH CLAIM FOR RELIEF

California Common Law Fraud

Against All Defendants

558. Plaintiffs re-allege and incorporate by reference paragraphs 1-356 of this Complaint as if fully set forth herein.

559. As alleged extensively above, Defendants knowingly and affirmatively misrepresented and/or concealed and suppressed material facts concerning the following: (a) bribes, disguised as donations, Jazz provided to CVC; (b) CVC's role as a conduit for Jazz, as opposed to an independent charity; (c) the role Defendants played in the volume of the Jazz Drugs purchased, including but not limited to Jazz asserting impermissible control or influence over CVC; (d) the inflated prices charged by Jazz for the Jazz Drugs.

560. Defendants valued profits over the trust of beneficiaries of Assignors and the Class Members who purchase the Jazz Drugs in California and other locations throughout the United States.

561. Necessarily, Defendants took steps to ensure that their employees did not reveal the details of their Co-Payment Scheme to consumers, including Assignors and the Class Members.

562. Defendants knowingly made false representations and omissions that were material to Assignors and the Class Members.

563. Assignors and the Class Members reasonably relied on Defendants' deception, and Defendants intended that they would so rely.

564. Assignors and the Class Members had no way of discerning that Defendants were, in fact, deceiving them because they possessed exclusive knowledge regarding the nature of the Co-Payment Scheme, intentionally concealed the foregoing from Assignors and the Class Members, as well as the public, and made incomplete or negligent representations about the Co-Payment Scheme and Jazz's relationship with CVC, while purposefully withholding material facts from Assignors and the Class Members that contradicted these representations.

1 565. Defendants' actions, representations, and misrepresentations demonstrate callous
2 disregard for the rule of law and the public trust of the health care system.

3 566. Indeed, as a direct result of Defendants' actions, the prices of the Jazz Drugs
4 skyrocketed, making the drugs unaffordable for many patients and caused many patients to forgo,
5 delay, or unilaterally reduce their treatments. Instead of lowering the price or giving these financially
6 needy patients access to Jazz's free drug program, Defendants instead created an elaborate scheme to
7 bilk Assignors and Class Members while purported to offer "free" drugs to patients.

8 567. Defendants owed Assignors and the Class Members a duty to disclose, truthfully, all
9 the facts concerning the Co-Payment Scheme described herein, the increased volume and price of the
10 Jazz Drugs, and Defendants' roles in causing such impermissibly increased volumes and prices.

11 568. Defendants hatched their deceptive Co-Payment Scheme and knew that their
12 customers, including Assignors and the Class Members, did not know about (and could not reasonably
13 discover) the manner in which Defendants intended to artificially inflate the volume and price of the
14 Jazz Drugs.

15 569. Defendants not only concealed all the facts concerning the Co-Payment Scheme
16 described herein but went further to make affirmative misrepresentations in communications to the
17 OIG about CVC's compliance with OIG regulations.

18 570. Defendants engaged in this fraudulent concealment at the expense of Assignors and
19 the Class Members, inducing Assignors and the Class members to rely on such, to their detriment.

20 571. Assignors and the Class Members were not aware of the concealed material facts
21 referenced above, and they reasonably relied on Defendants' representations.

22 572. As a direct and proximate result of Defendants' Co-Payment Scheme, Plaintiffs and
23 the Class Members sustained damages, including but not limited to paying for claims for the Jazz
24 Drugs tainted by AKS and FCA violations, inflated prices for the Jazz Drugs and excessive and
25 inflated volumes of the Jazz Drugs.

26 573. Defendants are liable to Plaintiffs and the Class Members for damages in an amount
27 to be proven at trial.

6. Awarding such other legal or equitable relief as the Court deems just and proper.

JURY DEMAND

Plaintiffs and the Class Members demand a jury trial on all claims so triable under Federal Rule of Civil Procedure Rule 38.

Respectfully Submitted,

/s/ Alex R. Straus

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APPENDIX

Plaintiff MSPRC's Assignment to Demonstrate Standing

1
2
3 1. Certain series of MSPRC executed irrevocable assignments of any and all rights to
4 recover payments made on behalf of their Assignors' Enrollees and health plan members. These
5 assignments authorize the designated series, and in turn MSPRC through its LLC Agreement, to
6 pursue and enforce all legal rights of recovery and reimbursement for health care services and
7 benefits. MSPRC alleges the below assignment to demonstrate standing.

8 2. On May 12, 2017, **SummaCare, Inc. ("SMCR")** irrevocably assigned to MSP
9 Recovery, LLC all its rights to recover against any liable third party (including RICO Defendants)
10 for payments made on behalf of its Enrollees ("SMCR Assignment"). Specifically, the SMCR
11 Assignment states the following:

12 [SMCR] hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP
13 Recovery, and any of its successors and assigns, any and all of [SMCR]'s right, title, ownership and
14 interests in and to all Claims existing on the date hereof, whether based in contract, tort, statutory
15 right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover
16 monies for [SMCR] that [SMCR] had, may have had, or has asserted against any party in connection
17 with the Claims and all rights and claims against primary payers and/or third parties that may be liable
18 to [SMCR] arising from or relating to the Claims, including claims under consumer protection statutes
19 and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims[.]"

20
21 3. On June 12, 2017, MSP Recovery, LLC irrevocably assigned all rights acquired under
22 the SMCR Assignment to Series 16-11-509, a designated series of MSPRC ("Series 16-11-509
23 Assignment"):

24 Assignor ... irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee
25 and its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to
26 the [Assigned Claims] (and all proceeds and products thereof) as such terms are defined in the [SMCR
27 Assignment.]

28 4. SummaCare, Inc. consented to, acknowledged, approved, and ratified the Series 16-
11-509 Assignment, which is memorialized in a letter dated September 5, 2018.

1 5. Consideration was given between each party in executing the SMCR Assignment and
2 the Series 16-11-509 Assignment.

3 Respectfully Submitted,

4 /s/ Alex R. Straus

5 Alex R. Straus (SBN 321366)

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CERTIFICATE OF SERVICE

Pursuant to Civil L.R. 5-5, I hereby certify that on April 3, 2023, a copy of the foregoing was filed electronically on the Court's CM/ECF system, and service was effected electronically to all counsel of record.

Dated: April 3, 2023

By: /s/Alex R. Straus